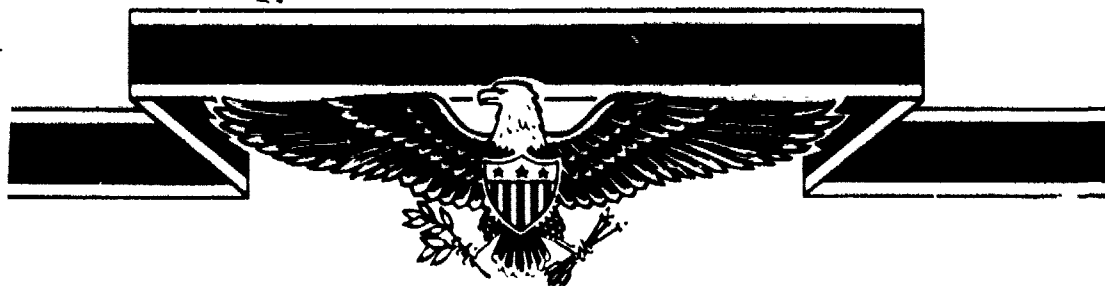


AD-A231 780



DEPARTMENT OF CLINICAL INVESTIGATION

# ANNUAL RESEARCH PROGRESS REPORT

FISCAL YEAR 1990  
VOLUME I

BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON, TEXAS 78234

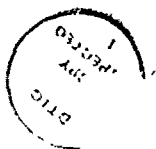
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20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Subject report identifies the research activities conducted by Brooke Army Medical Center investigators through protocols approved by the Clinical Investigation Committee, the Institutional Review Board, and the Animal Care Committee and registered with the Department of Clinical Investigation during FY 1988. Report also includes known presentations and publications by the Brooke Army Medical Center staff. The research protocols described were  (continued on reverse side)		

Block 20. Abstract

conducted under the provisions of AR 40-38, Clinical Investigation Program; AR 40-7, Use of Investigational Drugs in Humans; USAMRDC 70-25, Use of Volunteers as Subjects of Research; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports; and BAMC Memo 40-98, Department of Clinical Investigation, to insure the medical well-being, preservation of rights and dignity of human subjects who participated in these investigational studies. Research studies involving the use of laboratory animals were conducted under the provisions of AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs.



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## FOREWORD

The 1989-1990 year in the Department of Clinical Investigation (DCI) at Brooke Army Medical Center (BAMC) was both a very productive year and a year of transition. April 1990 saw MAJ Ricky D. Latham move to Brooks AFB to continue his research efforts, and June saw MAJ David L. Danley PCS to Fort Detrick. He has been ably succeeded in his administrative duties by LTC Robert G. Whiddon, Jr. who continues to manage the laboratory as well. CPT Earl Grant will be joining us in January 1991 upon completion of his Ph.D. training in biochemistry as a laboratory officer. With the retirement of COL Theopolis Peace, MAJ Denver Marlow joins us as the veterinary officer at BAMC. This smooth transition of leadership and the continuing productivity of this department is due to the support from the members of DCI and from the Commander, BG William L. Moore, Jr.; the Deputy Commander for Clinical Services, COL Thomas P. Hamilton II; the Deputy Commander for Administration, COL L. J. Eason; and the program chairmen.

The philosophy of this department is to support and encourage the academic interests of the residents in training and the entire professional staff. The performance of quality research is but one facet of this goal. Other facets include intellectual curiosity, the ability to design studies, the ability to analyze data, the ability to interpret results, the ability to express these efforts in written and oral form, and the ability to critically analyze scientific literature. It is our goal to assist in developing and supporting these tools not only in the academic and the scientists but also in the clinician with the belief that a continuing interest in research promotes continuing education and ultimately benefits the patient. In keeping with this goal, Drs. Jean Johnson, John Ward, and Robert Whiddon have been instrumental in developing a package of instructions that has been presented to several of the clinical services.

Work continues on the animal facility with the expectation that actual construction will occur in 1991. This increase in our capability is sorely needed as the numbers of animal use protocols continue to increase.

This year has seen a dramatic increase in the acquisition of extramural funding to support educational endeavors at BAMC. This department has been able to serve as a resource and support service for the investigator for obtaining these funds.

Some of our goals for 1991 include increased efforts in obtaining extramural funding and a broadening of the teaching program instituted this year to include a discussion of ethics in both science and medicine.

This has been a fruitful year for this department. Both LTC Whiddon and myself are indebted to the people in DCI and throughout BAMC who have supported, assisted and educated during the past few months. We are also grateful to those who preceded us and whose efforts made much of this year's progress possible. We look for another year of progress and service to the BAMC community.

*Charles P. Kingsley*

CHARLES P. KINGSLEY

Major, MC

Chief, Department of Clinical Investigation



COMMANDER'S AWARD WINNERS

**First Place**

The Effects of Ketamine and Thiopenal on  
Myocardial Contractility and Function  
in Hypovolemic Swine

Sanford M. Silverman  
Captain, MC  
Anesthesia and Operative Service  
Department of Surgery

**Second Place**

Prophylaxis of Implantation  
Transitional Cell Carcinoma  
with Intraperitoneal Chemotherapy

Kurt Hansberry  
Major, MC  
Urology Service  
Department of Surgery

**Third Place**

Viability of Skin Flaps Subjected to  
Simultaneous Chemical Peel with  
Occlusive Taping

David K. Hayes  
Major, MC  
Otolaryngology Service  
Department of Surgery

## UNIT SUMMARY - FISCAL YEAR 1990

### A. Objectives

The objectives of the Department of Clinical Investigation are as follows:

1. To achieve continuous improvement in the quality of patient care.
2. To assist in the professional growth and development of the house staff by providing guidance and support in clinical research.
3. To provide a milieu conducive to retention of competent staff personnel and recruitment of new personnel.
4. To provide a review body for research proposals by investigators currently assigned to MEDDAC Units in an effort to promote an interest in Army medicine and retention in the Army Medical Corps.
5. To maintain an atmosphere of inquiry consistent with the dynamic nature of the health sciences.
6. To maintain a high professional standard and accreditation of advanced health programs.
7. To assure the highest level of professional standards in the conduct of human research and animal research.

### B. Technical Approach

All research, investigational and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-7, AR 40-38, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with the applicable regulations.

### C. Staffing

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Latham, Ricky D.**	MAJ	61F	Chief, Cardiologist
Kingsley, Charles P.*	MAJ	60N	Chief, Anesthesiologist
Peace, Theopolis	COL	64B	Veterinary Lab Animal Officer
Whiddon, Robert G., Jr.	LTC	68A	Microbiologist
Danley, David L.**	MAJ	68E	Immunologist
Marlow, Denver D.*	MAJ	64B	Veterinary Lab Animal Officer
Jones, Sheila	SSG	92B3R	NCOIC
Diaz, Noel	SSG	92B3R	Med Lab Specialist
Hinds, Johnny W.	SSG	92B3	Med Lab Specialist
Parooqui, Muhammed**	SSG	92B2	Med Lab Specialist
Duncan, Rory D.	SGT	92B2	Med Lab Specialist
Gaines, Marlene**	SGT	91T2	Animal Care Specialist
Park, Chung***	SGT	91T2	Animal Care Specialist

### C. Staffing (continued)

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Cardona, Rene*	SSG	91T	Animal Care Specialist
Ruiz, Javier*	PV2	91T	Animal Care Specialist
Yoquelet, Curtis*	SFC	91T	Animal Care Specialist
Merrill, Gerald A.	GS11	00401	Research Immunologist
Ayala, Eleanor	GS11	00644	Medical Technologist
Grassel, Janice	GS11	00404	Biological Laboratory Technician
Ward, John A.	GS13	00401	Research Physiologist
Johnson, Jean A.	GS12	00610	Research Nurse
Reeb, Barbara	GS11	00644	Medical Technologist
Chapa, Isidoro	GS7	00645	Medical Technician
Williams, Dannie	GS7	00404	Biological Laboratory Technician
Rios, Roberto	GS9	01020	Medical Scientific Illustrator
Bratten, Dodie	GS9	00301	Clin Research Protocol Coord
Smith, Helen J.	GS6	01087	Editorial Assistant

\* Assigned Apr 90; Sep 90; Nov 89; Jan 90; Aug 90

\*\* Reassigned Apr 90; Jun 90

\*\*\* REFRAD Oct 89

Personnel:	Authorized	Required	Assigned
Officers -	4	9	4
Civilians -	10	16	10
Enlisted -	8	10	10

### D. Funding

Type	Fiscal Year 89	Fiscal Year 90
Civilian personnel to include benefits	257,615.00	396,324.00
Consumable supplies	128,200.00	120,000.00
Civilian contracts to include consultants	13,291.00	6,328.00
TDY	2,690.00	7,350.00
Noninvestment equipment (Minor MEDCASE)	-----	-----
Other OMA		
OMA Total	399,106.00	530,002.00
MEDCASE	95,000.00	279,900.00
Other		
Military	680,215.00	513,332.00
TOTAL	1,174,321.00	1,323,234.00

Grants:

- a. U.S. Army Medical Research and Development Command - \$145,830.00
- b. Air Force Surgeon General - \$43,435 00
- c. Air Force Office of Scientific Research - \$350,000.00
- d. DOD/VA Grant - \$20,000.00
- e. Southwest Oncology Group - \$25,000.00
- f. NCI/NIH Grant (Dermatology Service for the Isotretinoin Study)

Protocol Disposition FY 90

	<u>Terminated</u>	<u>Transferred</u>	<u>Completed</u>	<u>Ongoing to FY 91</u>
FY 77	-		0	1
FY 78	0		1	0
FY 83	0		0	1
FY 84	0		2	0
FY 85	1		1	1
FY 86	4		2	2
FY 87	5		6	12
FY 88	13		11	13
FY 89	27		34	55
FY 90	<u>8</u>		<u>12</u>	<u>105</u>
	58		79	190

Training Protocols

	<u>Terminated</u>	<u>Completed</u>	<u>Ongoing to FY 90</u>
FY 85	0	0	1
FY 86	2	0	4
FY 87	0	1	6
FY 88	0	0	1
FY 89	0	0	3
FY 90	<u>0</u>	<u>0</u>	<u>4</u>
	2	0	19

Oncology Group Protocols

SWOG	0	26	109
PCG	0	13	59
GOG	<u>0</u>	<u>0</u>	<u>19</u>
	0	39	187

Number of resident and fellowship programs: 23  
Number of residents and fellows with approved protocols: 84  
Number of approved protocols held by this group: 116

Other training programs that use Clinical Investigation: University of Texas Health Science Center at San Antonio; University of Texas, Austin; Academy of Health Sciences Physical Therapy Branch; University of Texas, Houston.  
Number of approved protocols held by this group: 22

Number of hospital staff members with approved protocols: 77  
Number of approved protocols held by this group: 189

Drug evaluation/comparison studies: 41 (Does not include Oncology Group Protocols)

#### Significant Changes in the Last Year/Changes for the Future

The department has received funding for a new temporary building to house small animals. This facility will double our small animal surgery capability.

We have become more pro-active in recruiting investigators in the MEDCEN. Workload at the animal facility has increased over 400% as compared to FY 89.

We are seeking opportunities to teach research technique within hospital departments. We have developed an 8 hour workshop for department sized groups. We plan to prepare single topic lectures to present and plan to videotape these lectures for viewing at home.

We are expanding our collaborative efforts with extramural sources. MRDC, the University of Texas Health Science Center, and State Chest Hospital are all collaborators.

The clinical research nursing program has initiated new protocols and the nursing staff at BAMC are being included in the research planning and execution of these studies, and more nurses are entering into collaborative studies.

#### Changes in Support of Growing Graduate Medical Education Requirements

We are aware of the growing requirement to have documented classroom hours devoted to research topics such as ethics, statistics, informed consent, protocol development etc. These requirements are being met by going to the departments and offering tailored instruction for each unit's needs.

We are increasingly taking advantage of gifts and grants offered through the Jackson foundation and organizations such as Facilitators of Applied Clinical Trials (F.A.C.T.) and other not for profit organizations. These efforts are slowed by the requirements for lengthy approval chains for relatively small amounts, but progress is being made in the utilization of these resources.

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DEPARTMENT OF THE ARMY  
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DEPARTMENT OF CLINICAL INVESTIGATION

PRESENTATIONS

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Danley, David L. Use of Flow Cytometry to Demonstrate a Possible Chloramine-dependent Effect on Microbial Nucleic Acids. Society of Armed Forces Medical Laboratory Scientists, Baltimore, MD, 6-10 March 1990. (C)

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Coleridge, Samuel T. Putting It All Together. ACLS Course, Academy of Health Sciences, Fort Sam Houston, TX, February 1990

Dice, William H. Operation Just Cause. Global Medicine Conference, San Antonio, TX, February 1990.

Dice, William H. Site Management of a Multiple Casualty Incident. Tri-Service Symposium, San Antonio, TX, March 1990.

Dice, William H. Operation Just Cause. Tri-Service Symposium, San Antonio, TX, March 1990.

Dice, William H. The Role of Military Emergency Medicine Physicians in Panama. Society for Academic Emergency Medicine, Minneapolis, MN, May 1990.

Dice, William H. Strategic Approach to the Difficult Airway. 3rd International Conference on Emergency Medicine, Toronto, Canada, June 1990.

Dice, William H. Physician Extenders in EMS. ACEP Scientific Assembly, San Francisco, CA, September 1990.

Lovello, Katherine T. A Prospective Review; Nurse versus Computerized Directed Triage Algorithms. Scientific Academy of Emergency Medicine, Minneapolis, MN, May 1990.

Norris, Robert N. Venomous Snake Bite: A Medical Emergency. Internal Medicine Grand Rounds, Wilford Hall USAF Medical Center, Lackland AFB, TX, October 1989.

Norris, Robert N. Environmental Emergencies: Bites and Stings. JMMC 2nd Annual Nursing Symposium, Fort Sam Houston, TX, October 1989.

Norris, Robert N. DMI Board Practice Sessions. Tri-Service Symposium, San Antonio, TX, March 1990.

Norris, Robert N. Field Management of Venomous Snake Bites. Texas State Herpetological Conference, San Antonio, TX, March 1990.

Norris, Robert N. Venomous Snakes of Guyana. 41st Combat Hospital, Fort Sam Houston, TX, March 1990.

Smith, Brent A. Smokejumper Wilderness Rescue Missions. Experience of the North Cascade Smokejumper Base 1957-1988. Wilderness Medical Society Annual Scientific Meeting, Snowbird, UT, July 1990.

## DEPARTMENT OF MEDICINE

### Allergy and Immunology

Dyer, Philip D. Methotrexate in the Treatment of Steroid Dependent Asthma. American College of Allergy and Immunology, Orlando, FL, October 1989.

### Cardiology Service

Belbel, Roger J. Left Ventricular Ejection Time in Aortic Stenosis. 32nd Annual Meeting of the Society of Air Force Physicians, San Antonio, TX, 10-14 March 1990. (C)

Ebersole, Douglas G. Atrial Fibrillatory Wave Size and Left Atrial Enlargement: An Echocardiographic Analysis. 32nd Annual Meeting of the Society of Air Force Physicians, San Antonio, TX, 10-14 March 1990. (C)

Johns, Joseph P. Color Doppler Can Demonstrate Spontaneous Resolution of Femoral Pseudoaneurysms. 32nd Annual Meeting of the Society of Air Force Physicians, San Antonio, TX, 10-14 March 1990.

Topol, Eric J., Condos, William R., Lawrence E. Pupa, et al. A Randomized, Controlled Trial of Late (6-24 Hour) Hyperfusion for Acute Myocardial Infarction. University of Michigan, Ann Arbor, MI. September 1990. (C)

Wellford, Landon. Embolus in Transit. University of Texas Health Science Center, San Antonio, TX, 5 September 1990.

### Dermatology Service

Anderson, Lawrence L. Discoid Lupus Manifesting as Chronic Blepharitis. Annual Meeting of American Academy of Dermatology, San Francisco, CA, 2 December 1989.

Becker, Larry E. Tropical Dermatology. Global Medicine Course, USAF School of Aerospace Medicine, Brooks AFB, TX, 6 February 1990.

Becker, Larry E. Hanson's Disease. Global Medicine Course, USAF School of Aerospace Medicine, Brooks AFB, TX, 6 February 1990.

Becker, Larry E. Approach to Dermatology for the Non-Dermatologist. 41st Military Medical-Surgical Clinical Congress, Garmisch, West Germany, 24 May 1990.

Becker, Larry E. Life Threatening Dermatoses. 41st Military Medical-Surgical Clinical Congress, Garmisch, West Germany, 24 May 1990.

Becker, Larry E. Sexually Transmitted Dermatoses Update. 41st Military Medical-Surgical Clinical Congress, Garmisch, West Germany, 24 May 1990.

Becker, Larry E. Common Dermatologic Problems. 41st Military Medical-Surgical Clinical Congress, Garmisch, West Germany, 24 May 1990.

Becker, Larry E. Skin Cancer. 41st Military Medical-Surgical Clinical Congress, Garmisch, West Germany, 24 May 1990

Grabski, William J. Laboratory Workshop in Flap Surgery (Faculty). American Academy of Dermatology, San Francisco, CA, 2 December 1989.

Grabski, William J. Surgical Repair Panel (Intermediate Surgery Course). American Academy of Dermatology, San Francisco, CA, 3 December 1989.

Grabski, William J. Surgical Repair Panel (Intermediate Surgery Course). American Academy of Dermatology, San Francisco, CA, 3 December 1989.

Grabski, William J. Surgical Pearls. Uniformed Services Dermatology Seminar, Keystone, CO, 15 May 1990.

Grabski, William J. Full Thickness Skin Grafts. American Academy of Dermatology Summer Session, Boston, MA, June 1990.

Heller, Jeffrey J. Case Report: Calcinosis Cutis in S.L.E. San Antonio Dermatological Society Meeting, San Antonio, TX, 16 November 1989.

Hill, Jerry. Development of Epithelial Sheets Grown from Human Adult Skin, Characterization, and Subsequent Transplantation to a Human Recipient. Residents' Forum, Texas Dermatological Society, Corpus Christi, TX, 12 May 1990.  
(C)

Keller, Richard A. Case Presentation Bullous Lupus Erythematosus. San Antonio Dermatological Society, San Antonio, TX, 26 October 1989.

Keller, Richard A. Case Presentation Silicone Granuloma. Southern Medical Society of Dermatology, Washington, D.C. 6 November 1989.

Keller, Richard A. DIC Secondary to Chromobacteriosis. 15th Annual Uniformed Services Dermatology Seminar, Keystone, CO, May 1990.

Keller, Richard A. Fibroepithelioma of Pinkus. 15th Annual Uniformed Services Dermatology Seminar, Keystone, CO, May 1990.

Keller, Richard A. Bullous Systemic Lupus Erythematosus. 15th Annual Uniformed Services Dermatology Seminar, Keystone, CO, May 1990.

Keller, Richard A. Nodular Elastosis. 15th Annual Uniformed Services Dermatology Seminar, Keystone, CO, May 1990.

Keller, Richard A. Acral Lentiginous Malignant Melanoma. 15th Annual Uniformed Services Dermatology Seminar, Keystone, CO, May 1990.

Lewis, Charles W. U.S. Military Initial Entry Fitness Standards. Annual U.S. Military Entrance Processing Command Chief Medical Officer Conference, 17 May 1990.

Lewis, Charles W. What's New in Dermatology Therapy. Uniformed Services Dermatologic Seminar, Keystone, CO, 15 May 1990.

Lewis, Charles W. Dermatologic Conditions that Disqualify for Military Service. U.S. Military Entrance Process Command, San Antonio, TX, May 1990.

Rosenmeier, Gary J. Proliferating Trichilemmal Tumor. American Academy of Dermatology, San Francisco, CA, 2 December 1989.

Sharkey, Michael J. Case Presentation of Favre Recouchot Disease. San Antonio Dermatological Society, San Antonio, TX, 26 October 1989.

Smith, Wallace B. Cholesterolemboli Syndrome. San Antonio Dermatological Society, San Antonio, TX, 20 October 1989.

#### Gastroenterology Service

Sullivan, Harold H., Jr. Percutaneous Endoscopy Gastrostomy: A Three Year Experience of the Gastroenterology Service at Brooke Army Medical Center. Air Force Regional Meeting of the American College of Physicians, San Antonio, TX, March 1990. (C)

#### Hematology-Oncology Service

Burris, Howard A., III, O'Rourke, Timothy J. LY186641: Amelioration of Toxicity with an Alternate Schedule of Administration. American Society of Clinical Oncology, March 1990. (C)

Burris, Howard A., III, Wall, James G. Pharmacokinetics of the Topoisomerase I Inhibitor, SK&F 104864. American Society of Clinical Oncology, March 1990. (C)

Burris, Howard A., III. SKF 104864: Preclinical Studies of a New Topoisomerase I Inhibitor. American Society of Clinical Oncology, March 1990. (C)

Jenkins, Terry R., Zaloznik, Arlene J. Factors Influencing Eligibility for Clinical Trials. American Society of Clinical Oncology, March 1990.

Jenkins, Terry E., et al. Batanopride (BMJ 25801) for the Prevention of High Dose Cisplatin Induced Emesis: A Randomized, Double Blind Study of Two Dose Levels. University of Texas Health Science Center. (C)

Wall, James G., Burris, Howard A., III. Phase I Study of SK&F 104864, A Novel Topoisomerase I Inhibitor. American Society of Clinical Oncology, March 1990. (C)

#### Infectious Disease Service

McAllister, C. Kenneth. Newer Antibiotics. Madigan Army Medical Center Grand Rounds, Tacoma, WA, January 1990.

McAllister, C. Kenneth. Top Ten Sexually Transmitted Disease. Madigan Army Medical Center Grand Rounds, January 1990.

McAllister, C. Kenneth. Infectious Disease Problems in Selected Historical Figures. Tri-Service Infectious Disease Conference, Homestead, FL, March 1990.

McAllister, C. Kenneth. New Antimicrobial Agents. Medical Grand Rounds, Brooke Army Medical Center, Fort Sam Houston, TX, August 1990.

McAllister, C. Kenneth. Pneumonia. Medical Grand Rounds, Brooke Army Medical Center, Fort Sam Houston, TX, August 1990.

#### Nephrology Service

Charney, D.I., Gouge, S.F. Chemical Peritonitis Secondary to Vancomycin. National Conference on Peritoneal Dialysis, Dallas, TX, February 1990. (C)

Charney, D.I. Lack of Selenium Deficiency in Chronic Hemodialysis Patients. SAHP Annual Meeting, San Antonio, TX, March 1990. (C)

Charney, D.I. Cardiac Arrest Following Hypertonic Citrate Anticoagulation for Chronic Hemodialysis. American Society for Artificial Internal Organs, Washington, D.C., April 1990

Gouge, S.F. The Quality of Life in End-Stage Renal Disease. Renal Grand Rounds University of Texas Health Science Center, June 1990. (C)

McConnell, E.L. Acute Milk-Alkali Syndrome Precipitated by Over-the-Counter NSAID's. SAHP Annual Meeting, San Antonio, TX, March 1990.

#### Neurology Service

Sinoff, Stuart. Visual Perseveration. Neurology Grand Rounds, University of Texas Health Science Center, San Antonio, TX, 29 March 1990.

Halliday, Alan. Headache Management for the Family Physician. Family Practice Grand Rounds, Carswell Air Force Base, Fort Worth, TX, 23 July 1990.

#### Pulmonary Disease Service

Anders, Greg T. Short-Term Follow-up in HIV Patients with Tuberculosis Infection Chemoprophylaxed with INH. Air Force Regional Meeting, American College of Physicians, San Antonio, TX, 12 March 1990. (C)

Ouellette, Daniel R. TNF- Elaboration by Human Alveolar Macrophages. Texas Thoracic Society, Austin, TX, 7 April 1990. (C)



#### DEPARTMENT OF NURSING

Brazil, Ann. Innovative Integration in Quality Assurance. Oklahoma Quality Assurance Professionals, Oklahoma City, OK, June 1990

Brazil, Ann. Workshop "Innovative Integration in Quality Assurance." Montana Quality Assurance Professionals, Billings, MT, May 1990

Brazil, Ann. Innovative Integration in QA Workshop. Wyoming Quality Assurance Professionals, Jackson Hole, WY, May 1990.

Brazil, Ann. The Role of the Nurse Administrator in Quality Assurance. University of Texas at San Antonio School of Nursing, San Antonio, TX, March 1990.

Brazil, Ann. Quality Assurance for Nutrition Care Directors. Incarnate Word College, San Antonio, TX, July 1990.

Brazil, Ann. The Politics of Change. Fourth Annual JMMC Nursing Research Workshop, San Antonio, TX, March 1990.

Brazil, Ann. Quality Assurance in Discharge Planning. Annual Discharge Planning Conference of the Society for Hospital Social Work Directors, San Antonio, TX, October 1989.

Callich, Marianne. Helping Children Cope with Procedures. Pediatric-Oncology Grand Rounds, University of Texas Health Science Center, San Antonio, TX, November 1989. (C)

Chiminello, Catherine. The Role of the Clinical Specialist. University of Texas Health Science Center Nursing Seminar, San Antonio, TX, April 1990.

Chiminello, Catherine. Care of the Ostomy Patient. American Cancer Society/United Ostomy Association Training Course, San Antonio, TX, June 1990.

Delacruz, J. Stress Management Unit - Outpatient. Psychiatric Nursing Conference, San Antonio, TX, June 1990.

Delacruz, Jessie. Stress Management. Defense Mapping Agency Meeting, Fort Sam Houston, TX, July 1990.

Dolter, Kathryn J., Warren, Joseph P. Neurotrauma in the Multi-Trauma Patients: Systematic Triage, Assessment, and Intervention. University of Cincinnati, Cincinnati, O.

Dolter, Kathryn J. Hemodynamic Monitoring. Myocardial Infarction. Hemodynamic Case Study. University of Texas Health Science Center, San Antonio, TX, January 1990.

Dolter, Kathryn J. Determinants of Cardiac Functions: Output, Preload, Afterload, Contractility. University of Texas Health Science Center Basic Critical Care Course, San Antonio, TX, September 1990.

Dolter, Kathryn J. Hemodynamic Monitoring: Types, Insertion, Waveforms, Values. University of Texas Health Science Center Basic Critical Care Course, San Antonio, TX, September 1990.

Dolter, Kathryn J. Pump Failure: Myocardial Infarction. University of Texas Health Science Center Basic Critical Care Course, San Antonio, TX, September 1990.

Ertter, Amy M. Use of Pulse Oximeter to Detect Lower Limb Ischemia in Patients Treated with the Intra-Aortic Balloon Pump. Phyllis J. Verhonick Nursing Research Course, Washington, DC, April 1990.

Ertter, Amy M. Use of the Pulse Oximeter to Detect Lower Limb Ischemia in Patients Treated with the Intra-Aortic Balloon Pump. JMMC 2d Annual Nursing Research Conference, San Antonio, TX, March 1990.

Hayslett, Karen. An Update on Dialysis. Intravenous Nurses Society, Inc., San Antonio, TX, November 1989.

Jerney, Charlotte. Leadership Course. University of Texas Health Science Center, San Antonio, TX, November 1989.

Lewis, John V. A Comparison of Acuity Levels Among Neuroblastoma and Acute Nonlymphocytic Leukemia Patients Undergoing Autologous Bone Marrow Transplants with Other Patients in a Pediatric Intensive Care Unit. Phyllis J. Verhonick Nursing Research Course, Washington, DC, April 1990.

Ross, Susan. Vietnam - A Nursing Perspective. Tri-Service Symposium in Emergency Medicine, San Antonio, TX, March 1990.

Trafford, Antoinette. The Efficacy of Early Cardiac Rehabilitation. Fourth Annual Nursing Research Conference, Sponsored by ALMM VA, San Antonio, TX, September 1990.

Vaiani, Cheryl. Women, Infants and Children and the Army. U.S. Army Nurse Corps Consultants' Conference, Washington, DC.

Worden, Shirley. Workload Management System for Nurses. Workload Management System for Air Force Nurses, Keesler Air Force Base, Biloxi, MI, February 1990.

Zager, Lydia. Staff Nurse Job Satisfaction and Burnout Related to the Head Nurse Leadership Style. 1989 Nursing Breakthrough Conference, University of Texas, Houston, TX, November 1989.

#### DEPARTMENT OF PATHOLOGY AND ALS

Brown, Bruce F. Case Presentation: Subependymal Giant Cell Astrocytoma. San Antonio Society of Pathologists, San Antonio, TX, 4 September 1990.

Fitts, James M. Case Presentation: Chromoblastomycosis. San Antonio Society of Pathologists, San Antonio, TX, 4 September 1990.

Harper, Bradley N. Case Presentation: Pulmonary Blastoma. San Antonio Society of Pathologists, San Antonio, TX, 4 September 1990.

Nauscheutz, Karen K. Case Presentation: Ganglioglioma. San Antonio Society of Pathologists, San Antonio, TX, 4 September 1990.

Raval, Hansagauri. Aspiration Cytology Breast, Thyroid, Neck. Nehru Medical College, Belgai, Karnatak, India, 1-2 March 1990.

Raval, Hansagauri. Pulmonary Cytology of Benign and Malignant Lesions. Cytology Review Course, Wilford Hall USAF Medical Center, Lackland AFB, TX, April 1990.

Raval, Hansagauri. Cytopreparation and Aspiration Cytology. Cytology Review Course, Wilford Hall USAF Medical Center, Lackland AFB, TX, April 1990.

Wilkerson, James A. Case Presentation: Adenocortical Carcinoma. San Antonio Society of Pathologists, San Antonio, TX, 4 September 1990.

Wohler, John P. Case Presentation: Merkel Cell Tumor. San Antonio Society of Pathologists, San Antonio, TX, 4 September 1990.

#### DEPARTMENT OF RADIOLOGY

Heironimus, James D. Renal Scintigraphy. Alamo Area Society of Radiologic Technologists, San Antonio, TX, 9 March 1990.

Heironimus, James D. Emission Computed Tomography of the Brain. Recent Advances in Diagnostic Imaging and Percutaneous Surgery, San Antonio, TX, April 1990.

Heironimus, James D. The Captopril Radionuclide Renogram. Texas Medical Association, Corpus Christi, TX, 12 May 1990.

Pearson, Vincent D. Phase Analysis of Gated Equilibrium Cardiac Scintigraphy. San Antonio Society of Nuclear Medicine, San Antonio, TX, May 1990.

Timmons, James. Hyperthyroidism. University of Texas Health Science Center, San Antonio, TX, October 1989.

Timmons, James. SPECT Imaging of Brain. University of Texas Health Science Center, San Antonio, TX, November 1989.

Timmons, James. Functional Brain Imaging Using SPECT. Alamo Area Radiologic Technologists Society, San Antonio, TX, March 1990.

Timmons, James. Functional Brain Imaging. San Antonio Society of Nuclear Medicine, San Antonio, TX, May 1990.

## DEPARTMENT OF SURGERY

### Anesthesia and Operative Service

Baumgarten, Richard K. Anesthesia - Equipment and Techniques. First International Conference Anaesthesia and Critical Care in Disasters and War, London, Great Britain, 19 July 1990.

Baumgarten, Richard K. Hemotherapy I. University of Texas Health Science Center, San Antonio, TX, 10 August 1990.

Baumgarten, Richard K. Anesthesia Delivery Systems for Worldwide Deployment. Wilford Hall USAF Medical Center, Lackland AFB, TX, 20 September 1990.

Baxter, Gary S. Epidural Test Dose for Inadvertent Subarachnoid Injection. American Society of Anesthesiologists, New Orleans, LA, 14-18 October 1989. (C)

Castro, Timothy. Epidural Test Dose for Inadvertent Subarachnoid Injection. American Society of Anesthesiologists, New Orleans, LA, 14-18 October 1989. (C)

Castro, Timothy. The Lighted Stylet (Light Wand) Intubation: A Technique Worth Knowing. American Society of Anesthesiologists, New Orleans, LA, 14-18 October 1989. (C)

Castro, Timothy. Awareness, Recall and Dreams. University of Texas Health Science Center, San Antonio, TX, 1 February 1990.

Culling, Robert D. Incidence of Postdural Puncture Headache After Continuous Spinal Anesthesia. American Society of Anesthesiologists, New Orleans, LA, 14-18 October 1989. (C)

Culling, Robert D. Lightwand Guided Rapid Sequence Orotracheal Intubation. American Society of Anesthesiologists, New Orleans, LA, 14-18 October 1989.

Ducey, Joseph P. The Effects of Resuscitation with Hypertonic Saline-Dextran on Cerebral Function. American Society of Critical Care Anesthesiologist, New Orleans, LA, 13 October 1989. (C)

Ducey, Joseph P. Effects of Succinylcholine, Vecuronium, and Atracurium on Intracranial Hemodynamics in Swine. American Society of Anesthesiologists, New Orleans, LA, 14-18 October 1989. (C)

Fincher, Cecil W. Epidural Anesthesia Instruction and Demonstration. U.S. Army Community Hospital, Fort Polk, LA, 2 November 1989.

Hecker, Richard B. Airway Intubation. Staff and Faculty, Academy of Health Sciences, Fort Sam Houston, TX, 21 February 1990.

Kingsley, Charles P. Anesthesia for Austere Conditions and Other Aspects of Military Anesthesia. Harvard Medical School, Boston, MA, 3-4 April 1990.

Kingsley, Charles P. Glasnost 1989 - Anaesthesia in USSR. First International Conference Anaesthesia and Critical Care in Disasters and War, London, Great Britain, 19 July 1990.

Menk, Emil J. Intrathecal Bupivacaine and Tetracaine for Cesarean Section. American Society of Anesthesiologists, New Orleans, LA, 14-18 October 1989. (C)

Menk, Emil J. Chronic Pain Management. University of Tennessee Medical Center, Knoxville, TN, 15 April 1990.

Menk, Emil J. The Impaired Physician. University of Tennessee Medical Center, Knoxville, TN, 16 April 1990.

Menk, Emil J. Electrical Safety in the Operating Room. University of Texas Health Science Center, San Antonio, TX, 23 May 1990.

Menk, Emil J. Oxygen Supplies in the Disaster Area. First International Conference on Anaesthesia and Critical Care in Disasters and War, London, Great Britain, 19 July 1990.

Menk, Emil J. Combat Anesthesia. JMRTC, Heidelberg, FRG, 14 July 1990.

Menk, Emil J. Combat Anesthesia. JMRTC, Bad Toelz, FRG, 16 July 1990.

Olson, Kevin W. Inhalational Anesthesia Equipment for Austere Conditions. American Society of Anesthesiologists, New Orleans, LA, 14-18 October 1989.

Peterson, Richard E. Malignant Hyperthermia Update. U.S. Army Community Hospital, Fort Polk, LA, 1 November 1989.

Peterson, Richard E. Lightwand Intubation Update. U.S. Army Community Hospital, Fort Polk, LA, 2 November 1989.

Peterson, Richard E. Morbidity/Mortality Case Conference. U.S. Army Community Hospital, Fort Polk, LA, 3 November 1989.

Silverman, Sanford M. The Effects of Thiopental on Myocardial Contractility and Function in Hypovolemic Swine. Society of Cardiovascular Anesthesiologists, 15 May 1990.

Sprague, Robert S. Celiac Plexus Block. University of Texas Health Science Center, San Antonio, TX, 8 March 1990.

Strong, William E. Combat Anesthesia. JMRTC, Salt Lake City, UT, 12-13 May 1990.

Strong, William E. Combat Anesthesia. JMRTC, Heidelberg, FRG, 14 July 1990.

Strong, William E. Combat Anesthesia. JMRTC, Bad Toelz, FRG, 16 July 1990.

Wesley, R.L. The Pentothal Pain Test in the Differential Diagnosis of Low Back Pain. American Society of Anesthesiologists, New Orleans, LA, 14-18 October 1989. (C)

#### General Surgery Service

Jackson, Mark R. Abdominal Vascular Trauma. American College of Surgeon's Committee on Trauma, Resident's Paper Competition, Washington, DC, March 1990.

Mozingo, David W. The Effect of 6% Saline on Cerebral Hemodynamics Following Hemorrhage. Gary P. Wratten Surgical Symposium, Washington, D.C., April 1990.

Mozingo, David W. Thoracobiliary Fistula from an "Asymptomatic" Gallstone. Southwestern Surgical Congress, La Quinta, CA, April 1990.

Robertson, Frank M. Desmoid Tumors. University of Texas Health Science Center, San Antonio, TX, 28 September 1990.

#### Ophthalmology Service

Grimes, Steven. Pre-Operative Chemical Preparation of the Eye. Alamo City Clinical Ophthalmology Conference, San Antonio, TX, 2 March 1990.

Hacker, Henry D. Investigation of Automated Perimetry in the Evaluation of Patients for Upper Lid Blepharoplasty. Alamo City Clinical Ophthalmology Conference, San Antonio, TX, 2 March 1990. (C)

Hubickey, Walter J. CT Scan Characteristics of Three Likely Intraocular Foreign Bodies. Alamo City Clinical Ophthalmology Conference, San Antonio, TX, 2 March 1990.

Kietzman, Timothy. The Effect of YAG Capsulotomy on Visual Field Testing. Alamo City Clinical Ophthalmology Conference, San Antonio, TX, 2 March 1990.

Krolicki, Thaddeus J. Does Rapid Sequence Induction of Anesthesia with Succinylcholine Increase Intraocular Pressure? Alamo City Clinical Ophthalmology Conference, San Antonio, TX, 2 March 1990. (C)

Lloyd, William C. III. Seems Like Yesterday. Alamo City Clinical Ophthalmology Conference, San Antonio, TX, 2 March 1990.

Lloyd, William C. III. Session III. Trauma. Alamo City Clinical Ophthalmology Conference, San Antonio, TX, 2 March 1990.

Lloyd, William C. III. Diagnosis and Management of Sympathetic Ophthalmia. National Eye Trauma Symposium, Dallas TX, 20 April 1990.

Mein, Calvin E. Cataract and Glaucoma. Alamo City Clinical Ophthalmology Conference, San Antonio, TX, 2 March 1990.

Mein, Calvin E. Silicone Oil in Retinal Detachment Surgery: Early Results at Wilford Hall. Alamo City Clinical Ophthalmology Conference, San Antonio, TX, 3 March 1990.

Olsen, James M. Medulloepithelioma. Alamo City Clinical Ophthalmology Conference, San Antonio, TX, 2 March 1990.

Parks, Susan L. What's So Unusual About the Moebius Syndrome? Alamo City Clinical Ophthalmology Conference, San Antonio, TX, 2 March 1990.

White, William L. The Effect of Blinking on Tear Elimination as Evaluated by Dacryoscintigraphy. Alamo City Clinical Ophthalmology Conference, San Antonio, TX, 2 March 1990.

Wood, Dwight W. Transscleral Ciliary Sulcus Fixation of Posterior Chamber Intraocular Lenses: A New Technique. Alamo City Clinical Ophthalmology Conference, San Antonio, TX, 2 March 1990.

#### Orthopaedic Surgery Service

Coe, Jeffrey D. Potential Neurological Hazards with Interspinous Wiring in the Cervical Spine. Annual Meeting of the Cervical Spine Research Society, December 1989. (C)

Coe, Jeffrey D. Load to Failure Strengths of Spinal Implants in Osteoporotic Spines - A Comparison Study of Pedicle Screws, Laminar Hooks, and Spinous Process Wires. American Academy of Orthopaedic Surgeons, February 1990.

Simpson, Michael B. The Incidence of Permanent Upper and Lower Extremity Profiles in Active duty Officers in the United States Army.

#### Otolaryngology Service

Braaten, Jeffrey M. Dermal Graft Closure of Persistent Tracheoesophageal Fistula. American Academy of Otolaryngology Head and Neck Surgery Annual Meeting, San Diego, CA, September 1990.

Elledge, E. Scott. The Effects of Topical Oral Clindamycin Antibiotic Rinses on Bacterial Content of Saliva in Healthy Human Subjects. American Academy of Otolaryngology-Head and Neck Surgery, San Diego, CA, September 1990. Resident Research Award. (C)

Farrior, R.T. Surgical Principles of Facelift. American Academy of Otolaryngology Head and Neck Surgery, San Diego, CA, September 1990.

Gibbon, Donna. Ectopic Location of Esthesioneuroblastoma in the Ethmoid and Maxillary Sinus. American Academy of Otolaryngology Head and Neck Surgery, San Diego, CA, September 1990.

Murphy, T.P. Rhinorrhea After Neuro-Otologic Surgery. Southern Medical Association Meeting, Washington, D.C. 5 November 1989.

Murphy, T.P. Evaluation of Facial Nerve with Gadolinium Enhanced MRI During Bell's Palsy. American Academy of Otolaryngology Head and Neck Surgery, San Diego, CA, September 1990.

Stambaugh, Kweon I. Neuroblastoma: Blindness as Its Initial Presentation. American Academy of Otolaryngology Head and Neck Surgery, San Diego, CA, September 1990.

Stambaugh, Kweon I. The Outstanding Ear: Its Correction by the Combination Technique. Instruction Course the American Academy of Otolaryngology Head and Neck Surgery, San Diego, CA, September 1990.

Weiss, R. Low Grade Papillary Adenocarcinoma of Salivary Gland. American Academy of Otolaryngology

#### Peripheral Vascular Surgery Service

Olson, David W. Brachiocephalic Reconstruction BAMC Experience - 1973-1988. San Antonio Vascular Surgery Society, 28 September 1989.

#### Plastic Surgery Service

Young, Robert N. Flaps for Acute Burns. Texas Chapter of the American College of Surgeons, Austin, TX, 26 January 1990.

Young, Robert N. Burn Reconstruction. USAISR Spring Symposium, San Antonio, TX, 24-25 April 1990.

#### Urology Service

Caballero, Ramon. Cryptic Presentation of Germ Cell Tumors. South Texas Chapter of American College of Surgeons, 1990.

Phillips, Thomas. The Dose Response of Corticosteroids BCG Immunotherapy for Murine Transitional Cell Carcinoma (MVT-2). South Texas Chapter of American College of Surgeons, 1990. (C)

Thompson, Ian M. Screening for Transitional Cell Carcinoma of the bladder in Cigarette Smokers. American Urological Association, November 1989.

Thompson, Ian M. A Multivariate Case-Control Study of Survival Following Transurethral Resection of the Prostate. South Central Section of the American Urological Association, November 1989.

Thompson, Ian M. Extended Follow-up of Stage D1 Adenocarcinoma of the Prostate. South Central Section of the American Urological Association, November 1989.

Thompson, Ian M. Presentation of Patients Ultimately Succumbing to Carcinoma of the Prostate: Is Early Diagnosis with Digital Rectal Examination Possible? American Urological Association, New Orleans, LA, 1990.



Thompson, Ian M. The Economics of Screening for Carcinoma of the Prostate. Austin, TX, January 1990.

Thompson, Ian M. The Economics of Screening for Prostate Cancer. Second International Symposium on Recent Advances in Urological Cancer Diagnosis and Treatment, Paris, France, 27-29 June 1990.

#### Nutritional Care Division

Bathalon, Gaston P. Eating Disorders. Cole High School, Fort Sam Houston, TX, 5 March 1990.

Gray, Karen L. Supermarket Savvy. NCO Wives' Club, Fort Sam Houston, TX, 6 March 1990.

Gray, Karen L. Is Your Child Fit? Northeast Independent School District PTA, San Antonio, TX, 14 March 1990.

Hawkins, Karen E. Fast Food and Fat. Fort Sam Houston Elementary School, Fort Sam Houston, TX, 5 March 1990.

Manship, Ms. Prudent Diet. Fort Sam Houston Civilian Employees, 20 October 1989.

Manship, Ms. Restaurant Dining. United Methodis Church, San Antonio, TX, 25 August 1990.

Martin, Jullie D. Making the Most of Your Calories. Army Residence Community, San Antonio, TX, 16 March 1990.

Martin, Julie D. Dining Out Tips. Budge Dental Clinic, Fort Sam Houston, TX, 17 May 1990.

Money, Elizabeth A. Eating the Low Cholesterol Way. Recruiters' Wives Club, Fountain Plaza Hotel, San Antonio, TX, 14 October 1990.

Money, Elizabeth A. AHA Step I Diet. BAMC Health Fair, Fort Sam Houston, TX, 25 October 1990.

Money, Elizabeth A. Weight Control During Smoking Cessation. 5th Recruiting Battalion, Fort Sam Houston, TX, 1 December 1989.

Money, Elizabeth A. Behavior Modification. DENTAC, Fort Sam Houston, TX, 17 March 1990.

Money, Elizabeth A. Nutrition - Readiness - Inseparable. San Antonio Recruiters, San Antonio, TX, 5 January 1990

Money, Elizabeth A. Control of Cholesterol. Civilian Employees Budge Dental Clinic, San Antonio, TX 11 January 1990.

Money, Elizabeth A. Cholesterol Control. Civilian Employees Camp Stanley, San Antonio, TX, 18 January 1990.

Money, Elizabeth A. Nutrition and Dental Health. Cole Elementary School, Fort Sam Houston, TX, 1 February 1990.

Money, Elizabeth A. Battle of the Bulge. American Cancer Society, San Antonio, TX, 5 February 1990.

Money, Elizabeth A. Update on Battle of the Bulge. American Cancer Society, San Antonio, TX, 15 February 1990.

Money, Elizabeth A. Nutrition Awareness Kick-Off. Incarnate Word College, 17 March 1990.

Money, Elizabeth A. Basic Nutrition. 91C Class, Academy of Health Sciences, Fort Sam Houston, TX 25 March 1990.

Money, Elizabeth A. Health Protion Initiatives. Senior 94F NCOs, Academy of Health Sciences, Fort Sam Houston, TX, 17 April 1990.

Money, Elizabeth A. Basic Weight Reduction. Officers, NCOs, and Civilian Employees, Brooks AFB, TX, 19 April 1990.

Parker, Christine L. Nutritional Intervention in Acute and Chronic Renal Failure. Baptist Medical Center, San Antonio, TX, 5 May 1990.

Starks, Leonard. Cholesterol and Diet. Health Services Command Nursing Staff, Fort Sam Houston Officers' Club, Fort Sam Houston, TX, 6 June 1990.

Walker, Julian M. Nutrition for Children. Fort Sam Houston Day Care/Child Care Center, Fort Sam Houston, TX, 15 February 1990.

Walker, Julian M. Nutrition for Children. Fort Sam Houston Home Care Providers, Fort Sam Houston, TX, 26 February 1990.

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DEPARTMENT OF THE ARMY  
Brooke Army Medical Center  
Fort Sam Houston, TX 78234-6200  
DEPARTMENT OF CLINICAL INVESTIGATION

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DEPARTMENT OF CLINICAL INVESTIGATION

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#### **Physical Medicine and Rehabilitation Service**

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# Detail Summary Sheet

Date: 24 Sep 90 Proj No: C-46-85 Status: Terminated  
 Title: Isolation and Characterization of the Chlorinating Moiety of Aspergillus  
sp. and Penicillium sp.

Start Date 10 Jun 85	Est Comp Date:
Principal Investigator Gerald A. Merrill	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Victor Elysee, SGT Paul M. Horowitz, Ph.D.
Key Words: <u>Aspergillus</u> <u>sp.</u> <u>Penicillium</u> <u>sp.</u>	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$946.45
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): 1) To isolate a haloperoxidase from a readily available source which has characteristics that would enable it to be utilized in a chemiluminescent immunoassay system currently being developed under protocol C-45-83.

2) To gain understanding of the mechanism of action of haloperoxidase, so insight into the physiological roles of this class of enzymes (i.e., the microbicidal action) in various cell types (granulocytes, plants, fungi, etc.) can be gained.

Technical Approach: Selected fungi (Aspergillus sp. and Penicillium sp.) would be cultured in Czapek Dox media and homogenized. Following centrifugation, both supernatant and pellet would be assayed for haloperoxidase activity at various chloride/HOOH ratios at a series of pH's using a standard assay for halogenating activity employing monochlorodimedon. If a significant halogenating activity is detected further purification of the responsible enzyme would be initiated. The methods employed for purification would depend on gross characteristics of the enzyme such as pI, carbohydrate content, molecular weight, etc. The purified enzyme would then be tested for optimum conditions for HOOH dependent halogenation and for its ability to catalyze the chemiluminogenic dioxygenation of cyclic hydrazides (luminol derivatives) at various pH's and halide/HOOH ratios in an attempt to achieve a practical enzyme for use in development of a chemiluminogenic enzyme linked immunoassay system. Proposal of an enzyme mechanism of action would involve use of methods designed to show conformational changes in substrates and enzyme during catalysis, to include fluorescent techniques.

Progress: Due to lack of available time and personnel, no progress has been made on this study. As no available time to conduct the required work is foreseen for the next year, the project is terminated. A new protocol will be submitted at a later date when technician support becomes available.

# Detail Summary Sheet

Date: 25 Sep 90 Proj No: C-18-88 Status: Ongoing  
 Title: Development of an Indirect Chemiluminogenic Enzyme Linked Immunoassay (CELIA) for Demonstrating Conformational Changes in a Model Protein

Start Date 16 Dec 88	Est Comp Date:
Principal Investigator Gerald A. Merrill	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Paul M. Horowitz, Ph.D., UTHSC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 4690.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To develop monoclonal antibodies to rhodanese, a well characterized model protein, and use these antibodies in the development of an indirect soluble chemiluminescent enzyme linked assay system.

To assess the binding affinities of anti-rhodanese monoclonal antibodies for their epitopes and demonstrate conformational changes involving the rhodanese epitomes by monitoring changes in binding affinities.

Technical Approach: An assay has been developed for evaluation of the binding affinity with which MABs to rhodanese interact with their respective epitopes. Technical procedures are as outlined in the study protocol.

Progress: It is essential to understanding the conformational changes in a model protein detected through use of antibodies that the epitope recognized by each of the antibodies be mapped to a defined location in the protein's sequence. Three monoclonal antibodies (MABs) to rhodanese have been produced previously. It has been attempted to map their epitopes to digest fragments generated via CNBr digestion of the enzyme. Digestion has been shown to be essentially a limit digest. Using a slot blot approach where antibodies are allowed to bind to digest fragments adsorbed to immobilon membranes, it has been shown that two of the MABs (MAB11 and MAB14) bind to the total digest (digested rhodanese not subjected to any purification of fragments), but that R207 did not. It is assumed that an intact MET must be required for expression of R207's epitope. The digest was partly purified by size exclusion chromatography. The epitope of MAB11 was tentatively assigned to CNBr fragment II while MAB14's epitope is tentatively assigned to CNBr digest fragment III. R207 also failed to

C-18-88 (continued)

detect any fragments following digestion of rhodanese with iodobenzoic acid which cleaves at tryptophan residues. It was assumed from this that R207 also requires a TRP residue to express its epitope. The only occurrence of TRP and MET in close proximity to one another is in the junction of CNBr digest fragments II and III where a TRP MET sequence occurs. It is thus likely that this is the region recognized by R207. However, more definitive epitope assignments are warranted. This will require the additional digestion of rhodanese with papain or hydroxylamine to achieve a fragment to which R207 can bind. In addition, larger quantities of rhodanese will be digested with CNBr to allow isolation of digest fragments with sequential use of size exclusion and ion exchange columns.

Structural Changes in Oxidatively and Thermally Denatured Rhodanese:  
Immunological Evidence. Presented at University of Texas Health Science Center  
at San Antonio Research Seminar Series, 11 Sep 90.



# Detail Summary Sheet

Date: 9 Oct 90 Proj No: C-25-88 Status: Terminated  
 Title: Use of Fluorescence-Activated Flow Cytometry to Identify Bone Cells

Start Date 14 Jan 88	Est Comp Date:
Principal Investigator David L. Danley, MAJ, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Janice Grassel, M.T. Barbara Reeb, M.T. Gerald Merrill
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 929.65
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To determine the feasibility of using FACS to identify bone cells and to study their metabolic activities.

Technical Approach: In our initial study, we propose to use human or animal cell lines with known characteristics of osteoblasts: SAOS-2 (human), MT-3T3 (human, and ROS 17/2.8 (rats). They will be grown and passed under sterile conditions in the CI tissue culture facilities. To identify cell types and function, we will use a FACS 400.

Progress: No progress has been made since this study was activated. Now that the principal investigator has been reassigned, there is no one to pursue the study.

# Detail Summary Sheet

Date: 28 Sep 90 Proj No: C-12-89 Status: Completed  
 Title: An Investigation of Cell Wall Sulphydryl Groups and the Pathogenicity of Candida albicans

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator	Facility
David L. Danley, MAJ, MS	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Clinical Investigation	John Hinds, SSG
Key Words:	Gerald A. Merrill, GS-11
<u>Candida albicans</u>	Janice Grassel, GS-11
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To examine the significance of sulphydryl groups on the cell wall of C. albicans and the ability of this yeast to kill human monocytes or to be killed by human polymorphonuclear leukocytes (PMN).

Technical Approach: We treated yeast cells briefly with three chemicals that bind to -SH groups: N-ethylmaleimide (NEM), 4,4' dithiodipyridine, and iodoacetic acid. Cell viability by uptake of ethidium bromide (EB) and growth on cornmeal agar was measured. -SH groups were measured using fluorescein-5-maleimide (FM) and flow cytometry.

Progress: None of the -SH blocking agents altered EB uptake. However, NEM-treated cells failed to grow, and FM binding was reduced 87%. Incubating these cells in Sabouraud dextrose broth did not improve FM binding. Dithiodipyridine also reduced FM binding by 85%, but binding increased significantly after cells were incubated in broth, and cell growth was reduced 13%. Finally, iodoacetic acid reduced FM binding by 18%, it returned to normal when cells were incubated in both for 1 hour, and growth was reduced 8%. Inhibition of yeast cell growth by -SH blocking agents appears to be related to the nature of the agent and the metabolic activity of the cell.

"Different Responses by Candida albicans to Three Sulphydryl Blocking Agents."  
 Presented ASM Annual Meeting, 13-17 May 1990, Anaheim, CA.

# Detail Summary Sheet

Date: 19 Oct 90 Proj No: C-25-89 Status: Terminated  
 Title: Computer-Assisted Comparison of Data Tables Used to Identify Mycobacteria

Start Date 27 Jan 89	Est Comp Date:
Principal Investigator	Facility
Robert G. Whiddon, Jr., Ph.D., LTC, MS	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Clinical Investiation	S. V. Juchau, COL, MS
Key Words:	Joe Martinez, GS-09
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To find the most effective test method to identify mycobacteria. The test battery selected will then be used to identify clinical isolates in parallel with the current method and these identifications compared by using Pearson's correlation coefficient.

Technical Approach: Data will be collected from the literature on all tests reported to be useful in the identification of mycobacteria. This data set will be analyzed and compared to the data table currently used at BAMC to identify mycobacteria. Computer programs written by the principal investigator will be used to find the best combination of tests to be used. This optimum test battery will be compared to the one in use. The test battery selected from this process will then be used to identify clinical isolates in parallel with the current method and the results of these identifications compared by using Pearson's correlation coefficient.

Progress: Computer analysis of the of the data collected from the literature has been completed and the results presented at the American Society for Microbiology. One associate investigator (SVJ) has retired, and another (JM) is working in a laboratory with severe workload/manpower problems and has had little time to devote to eh laboratory testing portion of the study. Therefore, the study is terminated at this point.

# Detail Summary Sheet

Date: 19 Oct 90 Proj No: C-68-89 Status: Completed  
 Title: The Establishment of a Summary Database for the Autologous Bone Marrow Rescue Program

Start Date: 5 May 89	Est Comp Date:
Principal Investigator Robert G. Whiddon, Jr., LTC, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Richard Guidice, MAJ, MC Barbara Reeb, GS-09 Rory Duncan, SGT
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To identify data elements from autologous bone marrow rescue (ABMR) patient records that should be merged with the existing laboratory data generated during bone marrow processing.

Technical Approach: This merged file will generate ad hoc and permanent reports that will document the success of this program and provide a basis of comparison with other programs. This data will serve as a Quality Assurance instrument for the program and can provide an experience summary for other laboratories that set up ABMR procedures. Questions that are expected to be answered are the number and type of blood products used with this patient population, correlations between cell counts and viability and time to engraftment, and correlations between drugs and dose and engraftment.

Progress: The investigators have reviewed files retrieved from Patient Administration Division. Retrospective review of three records has been more difficult and less productive than expected. Data regarding the use of blood products for this patient population has been the most useful and has supported efforts to improve the quality assurance effort in the transplant program. The investigators feel that no further progress can be made by retrospective review.

# Detail Summary Sheet

Date: 28 Aug 90	Proj No: C-91-89	Status: Ongoing
Title: Development of a Standard Protocol for the Rapid Plasmid Profile Analysis of Bacterial Isolates		

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Gerald A. Merrill	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Robert G. Whiddon, LTC, MS Guy Plunkett, III, Ph.D.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To evaluate each of several procedures for the rapid isolation of bacterial plasmids, and to select one which reproducibly yields a wide size range of bacterial plasmids from a variety of bacterial strains likely to be bacterial pathogens.

Technical Approach: Bacterial test strains will be obtained from the Area Lab with no reference to the patient source. These strains will be grown overnight at 37°C in 5 ml of LB media to obtain adequate numbers of bacteria. The initial extraction process to be evaluated will be the method described by Holmes and Quigley. Subsequently this proved to be ineffective at lysing these bacterial isolates. A modified plasmid isolation technique which uses a combination of lysozyme and mutanolysis to weaken the bacterial cell walls was used. Bacteria are lysed by addition of 3N NaOH. Plasmid DNA is extracted by phenol and subsequently with chloroform:isoamyl alcohol.

Progress: Plasmid analysis was utilized to track an outbreak of methicillin resistant enterococcus at BAMC. The enterococcus isolates had two distinct pheotypes based on biochemical testing. More definitive evidence of the comonality of the isolates having the same plasmid profiles and biotypic expression will come from analysis of the DNA fragments produced by partial DNA digestion using a series of selective restriction endonucleases. These restriction endonucleases have been purchased, but at this time, DNA digestion and subsequent DNA fragment analysis on agarose gels has not been initiated.

# Detail Summary Sheet

Date: 19 Oct 90 Proj No: C-1-90 Status: Ongoing  
 Title: Development of Monoclonal Antibody from a 60-Kilodalton Oncofetal Tumor Marker Found in Plasma of Cancer Patients.

Start Date 14 Nov 89	Est Comp Date:
Principal Investigator Robert G. Whiddon, Jr., LTC, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: MAJ Donald E. Sutherland, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): SW60 holds promise as a general tumor marker for nearly all types of cancer. A good source of SW60 will allow assay for the tumor marker by immunoassay, rather than by bioassay and the use of a laboratory rat. This study hopes to identify carcinoma cells grown in suspension culture as a good source of SW60.

Technical Approach: Following autologous bone marrow harvest and adjusting the hematocrit prior to freezer storage, excess plasma which is normally discarded will be forwarded to MAJ Sutherland at DDEAMC for use in the development of monoclonal antibody.

Progress: Two shipments of excess plasma have been made to DDEAMC. The bioassay is able to detect evidence of SW60. Loss of technician support has slowed progress during the summer months.

# Detail Summary Sheet

Date: 28 Sep 90 Proj No: C-5-90 Status: Completed  
 Title: An Investigation of Some Biochemical Processes Used by Human Polymorphonuclear Leukocytes to Kill Candida albicans.

Start Date 7 Dec 89	Est Comp Date:
Principal Investigator David L. Danley, MAJ, MS	Facility Brooke Army Medical Center
Dept/Svc Dept. Clin. Investigation	Associate Investigators: Ms. Janice Grassel SSG Johnny Hinds Gerald A. Merrill
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): Human polymorphonuclear leukocytes (PMN) are candidacidal; i.e., c. albicans blastoconidia fail to germinate on cornmeal agar following incubation with PMN in vitro. Reportedly, there are two biochemical processes used by PMN to kill c. albicans: a non-oxidative mechanism involving cationic proteins (defensins) and an oxidative process involving myeloperoxidase (MPO), hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>), chloride (CL), and possibly ammonium. Data obtained in this laboratory, using flow cytometry and a fluorescent probe for cell viability, suggested that cationic proteins may kill yeast cells after prolong incubation, but MPO-H<sub>2</sub>O<sub>2</sub>-CL probably does not. Our objective is to measure several parameters of yeast cell physiology after cells have been incubated with these cytotoxic substances and ascertain how they affect metabolic activity.

Technical Approach: Flow cytometry is a versatile technique for studying cellular biochemical processes. We observed that Candida albicans yeast cells incubated with human polymorphonuclear leukocytes (PMN) stained poorly with ethidium bromide (EB), a vital stain that strongly fluoresces when bound to nucleic acid.

Progress: Yeast cells with PMN stained slightly better when catalase was present, but iron chelating agents had no effect. When viable yeasts were incubated with myeloperoxidase (MP), H<sub>2</sub>O<sub>2</sub>, and chloride, they stained intensely with EB; and the fungi did not grow on agar. When ammonium was added with these reactants to promote formation of monochloramine, yeast cells also failed to grow; but they stained poorly with EB. PMN generated chloramines during phagocytosis. Our results suggest that they may inhibit EB binding to NA which may reflect a biochemical change in the NA.

"Use of Flow Cytometry to Demonstrate a Possible Chloramine-dependent Effect on Microbial Nucleic Acids." Presented at The Society of Armed Forces Medical Laboratory Scientists meeting, April 1990, San Antonio, TX.

# Detail Summary Sheet

Date: 29 Nov 90 Proj No: C-7-90 Status: Ongoing  
 Title: Comparison of Noninvasive Venous Stop Flow CVP to Invasively Recorded Pressures

Start Date 7 Dec 90	Est Comp Date:
Principal Investigator Ricky D. Lathem, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Dept of Clinical Investigations	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review	Results

Objectivess): The primary purpose of this proposal is to compare the venous stop flow (VSF) technique for measuring central venous pressure to the invasive technique using a high-fidelity catheter, which is currently the gold standard. Second, we will evaluate the accuracy of estimates of the zero level for fluid pressure reference. Finally, we will evaluate the physiologic effects of the VSF technique on cardiac chamber sizes, intracardiac pressures and IVC flow.

Technical Approach: During elective catheterization, the interjugular doppler velocity is recorded during forces exhalation to a specified pressure. The pressure levels are recorded in stepwise fashion. NASA-JSC investigators will read the data tapes blinded to actual CVP measurements. A comparison of noninvasive CVP will be made to invasive CVP recording.

Progress: Three subjects enrolled to date. Data analysis is pending review at NASA-JSC.



# Detail Summary Sheet

Date: 29 Nov 90 Proj No: C-16-90 Status: Ongoing  
 Title: Evaluation of Central Hemodynamics During the L1 Anti-G Straining Maneuver.

Start Date 18 Jan 90	Est Comp Date:
Principal Investigator Ricky D. Latham, MAJ	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$50,340.00 (R&D)
Number of Subjects Enrolled During Reporting Period: 5	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review	Results

Objective(s): 1) Evaluate left and right heart blood pressures and flows during two components of the standard L1 anti-G straining maneuver: an abdominal strain and peripheral muscle strain. 2) Measure SVC and IVC flows by noninvasive doppler to determine the effects as a function of time on venous return by this maneuver. 3) Evaluate blood pressure response by noninvasive mens in the operational environment with and without straining.

Technical Approach: In part 1 of the study, 10 patients age 20-55 undergoing routine cardiac catheterization will be asked to perform several Valsalva maneuvers. At the same time blood pressure and flow velocity will be recorded.

In part 2 of the study, 10 healthy Army aviators, age 20-55, will be asked to wear a noninvasive portable blood pressure device to record blood pressures during flight in a high performance helicopter. An accelerometer will be used to record the g stresses encountered. A minimum of five flights will be used for the study.

Progress: Preliminary analysis done on first subjects entered. Data presented at IVPs Commission on Gravitational Physiology.

Need five more subjects for catheterization. Part 2 of the study is awaiting arrival of hardware.

# Detail Summary Sheet

Date: 9 Aug 90 Proj No: C-93-89 Status: Completed  
 Title: The Occurrence of Bacteremia Associated with Osseointegrated Endosteal Implants

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator John R. Scuba, MAJ, DC	Facility Brooke Army Medical Center
Dept/Svc Department of Dentistry/Oral Surgery	Associate Investigators: John P. McLaughlin, LTC, DC William P. Mills, LTC, DC William F. Nauscheutz, CPT, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 17	
Total Number of Subjects Enrolled to Date: 17	
Date of Periodic Review _____ Results _____	

Objective(s): To determine whether states of bacteremia exist subsequent to the emplacement of intraoral implants, either immediately postoperatively or after a prolonged healing phase.

Technical Approach: Patients participating in the study were oral and maxillo-facial surgery inpatients and outpatients receiving osseointegrated endosseous intraoral implants in preparation for prosthodontic restoration of missing teeth. After healing of intraoral tissues and loading of implants with a dental prosthesis, blood was drawn for aerobic and anaerobic culture. The patient was asked to masticate vigorously for five minutes and a second blood sample obtained five minutes subsequent to cessation.

Progress: Seventeen patients had blood cultures drawn anywhere from four weeks to several months after the insertion and loading of transoral mucosal endosseous implants of the jawbones. Of these patients, only one culture was returned as being positive for an aerobic bacterium which was felt to be a contaminant in the acquisition of the sample. Repeat blood culture was negative.

Conclusions: It is highly unlikely that well-healed transoral mucosal endosseous implants result in significant bacteremias under masticatory forces.

# Detail Summary Sheet

Date: 18 Jul 90      Proj No: C-63-87      Status: Completed  
 Title: Role of Routine Radiographs in the Evaluation of Acute Knee Complaints  
 in the Emergency Department

Start Date 25 Jun 87	Est Comp Date:
Principal Investigator MAJ Robert L. Norris, Jr.	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Peter Curka, CPT, MC A.C. Saxena, CPT MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To develop a set of high-yield criteria based on a careful history and physical examination in patients with acute knee complaints that will guide Emergency Department physicians in the ordering of knee radiographs.

Technical Approach: Between May 1987 and January 1990, 616 consecutive patients over the age of 15 years with knee complaints of less than one week were evaluated using a standardized history and physical examination format. Based on the history and physical, physicians noted any specific radiographic findings they expected. All patients received standard AP and lateral views of the involved knee. Upon reviewing the films, the physicians were asked whether radiographs altered their management of the patients.

Progress: Unsuspected fractures were discovered in ten patients (1.6%) and radiographs were normal in 32 patients (5.2%) in whom fractures were suspected clinically. The radiographs were felt to have altered the management of the patient in 51 cases (8.3%). Using correlation analysis, we found the absence of 6 factors to be predictive of normal radiographs: immediate swelling, ecchymosis, effusion, deformity, increased warmth, and abrasion/laceration. Further research employing these criteria in a prospective fashion is necessary before any firm recommendations can be made.

# Detail Summary Sheet

Date: 25 Oct 90 Proj No: C-73-87 Status: Completed  
 Title: The availability of Antivenin (Crotalidae) Polyvalent and Antivenin (Micrurus fulvius) in Texas Hospitals Providing Emergency Medical Care

Start Date 12 Aug 87	Est Comp Date:
Principal Investigator Robert L. Norris, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words: Antivenin	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To attempt to determine the actual supply and availability of antivenins against the venomous snakes indigenous to Texas in hospitals providing emergency medical care in the State.

Technical Approach: A questionnaire will be sent to all pharmacy directors of hospitals in the State of Texas. The pharmacy director will be asked to quantify his/her facility's antivenin supply currently in stock. Simultaneously, a questionnaire will be mailed to all directors of Emergency Departments/Emergency Rooms of hospitals in the State. They will be asked several pertinent questions regarding their facility's approach to the management of snakebite victims.

Progress: This study has been completed. However, no information is available as the principal investigator has been released from active duty.

# Detail Summary Sheet

Date: 20 Aug 90 Proj No: C-89-87 Status: Terminated  
 Title: Prognostic Predictive Value of the Clinical/Hemodynamic Classification Schema of Left Ventricular Performance in Acute Myocardial Infarction Determined at the Time of Presentation and 72 Hours Post-Admission

Start Date 21 Sep 87	Est Comp Date:
Principal Investigator Brenda A. Gowsky, CPT, USAF MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Ricky D. Latham, MAJ, MC Lawrence Pupa, MAJ, MC William Wright, CPT, MC
Key Words: Infarction, myocardial	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 Sep 90	Results Terminate

Objective(s): 1) To determine the predictive value of the Killip classification in acute myocardial infarction for short term prognosis.

2) To correlate the Forrester classification documented by invasive measurements as well as noninvasive assessment of left ventricular function with the Killip classification and prognosis.

Technical Approach: Patients arriving in the Emergency Room at BAMC with a chief complaint of chest pain and/or shortness of breath will be entered into the study. It is the object of this study to correlate noninvasive Killip with the invasive monitoring of the Forrester classification and to correlate these with hospital mortality and prognosis. Residents will assess the patient and complete a questionnaire.

Progress: This study was terminated due to inability to obtain the necessary cardiology support.

# Detail Summary Sheet

Date: 28 Sep 90 Proj No: C-42-89 Status: Ongoing  
 Title: Comparison of Light Reflection Rheography and Venography in the  
 Diagnosis of Acute Deep Venous Thrombosis

Start Date 28 Feb 89	Est Comp Date:
Principal Investigator (vice MacLean) Peter P. Taillac, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of	Associate Investigators: Kevin Rodgers, CPT, MC John M. Bauman, MAJ, MC Allan Morgan, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$6,000.00
Number of Subjects Enrolled During Reporting Period: 17	
Total Number of Subjects Enrolled to Date: 17	
Date of Periodic Review	Results

Objective(s): 1) To determine the applicability of Light Reflection Rheography as a screening tool for the detection of deep venous thrombosis in the emergency department.

2) To determine the sensitivity and specificity of Light Reflection Rheography when compared to venography in the diagnosis of acute deep venous thrombosis.

Technical Approach: Seventeen patients with clinical findings suspicious of deep venous thrombosis were evaluated with Light Reflection Rheography prior to receiving a venogram. Light Reflection Rheography data obtained from this group was evaluated in a blinded fashion and the results compared to venogram results.

Progress: Light Reflection Rheography was found to be 71% sensitive and 80% specific in making the diagnosis of lower extremity deep venous thrombosis. Light Reflection Rheography may prove to be an effective, inexpensive, simple, and noninvasive technique to aid in diagnosing lower extremity deep venous thrombosis in the Emergency Department setting. By increasing the sample size, sensitivity and specificity may be increased.

# Detail Summary Sheet

Date: 17 Jul 90 Proj No: C-84-89 Status: Completed  
 Title: The Efficacy of Steroid Burst Therapy in Reducing Severity of an Acute Migraine Headache

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Laurel I. Kietzman, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Sidney Atkinson, LTC, MC
Key Words: Migraine	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 13	
Total Number of Subjects Enrolled to Date: 13	
Date of Periodic Review	Results

Objective(s): To determine whether steroid burst therapy has any significant effect in the treatment of acute migraine pain when compared with placebo.

Technical Approach: Thirteen patients were randomized by a computerized random numbers program to receive either steroid burst (Prednisone, 4 mg daily for 5 days) or a placebo. At the initial visit, the patients defined the severity of their headache on a linear pain scale as well as a verbal scale. Patients were questioned as to whether they had received medications in the prior week and these were noted. They then received either dyhydroergotamine IV with Reglan, or promethazine 50-75 mg or hydroxyzine 50-75 mg intramuscularly. There were asked to reevaluate the severity of their headache prior to departure from the Emergency Room. The five day follow-up occurred either by phone or in the Neurologist's office, using the same verbal and linear scales.

Progress: In all, six patients were entered into the study group and seven patients received the placebo. Three patients in the placebo group returned to the Emergency Room within the five day period for re-treatment because their headaches had not subsided. One patient in the steroid group discontinued her therapy after two days because she felt her headach was getting worse. These four patients were graded as failures. The other patients either reported either partial or complete relief of their headaches.

Conclusion: No statistically significant difference was found between placebo and experimental groups. Further study of larger numbers of patients may enhance the statistical power of these findings.

# Detail Summary Sheet

Date: 29 Nov 90 Proj No: C-123-89 Status: Ongoing  
 Title: A Compound Curve Cutting Edge Needle for Skin Closure

Start Date: 31 Oct 89	Est Comp Date:
Principal Investigator Benjamin Walker, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Thomas P. Cook, 2LT, USAR
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To gather preliminary information regarding the usefulness to emergency physicians and residents of a newly designed skin closure needle.

Technical Approach: All patients with cutaneous lacerations presenting to the emergency department will be evaluated and treated in the usual manner. If wound closure is deemed necessary with either a 4-0 or 5-0 suture, a PS-2 compound curve needle with either a 4-0 or 5-0 nylon suture will be utilized to close the wound. The physicians will then be asked to fill out a questionnaire evaluating their satisfaction with the needle.

Progress: Evaluation continues. No reportable data are available at this time.



# Detail Summary Sheet

Date: 29 Nov 90	Proj No: C-9-90	Status: Ongoing
Title: Predictive Criteria in Geriatric Bacteremia		

Start Date 6 Dec 89	Est Comp Date:
Principal Investigator Douglas McDowell, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Resident Emergency Medicine	Associate Investigators: Samuel T. Coleridge, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine if there are "factors" at the time of presentation of the geriatric patient which are predictive of bacteremia.

Technical Approach: All patients admitted over age 65 for or with possible infections will be enrolled. Patients meeting inclusion criteria, as determined by routine physical examination and radiographic and laboratory studies, will have a single set of blood cultures drawn and other evaluations deemed necessary by the admitting physician. A physician assessment sheet will be completed at the time of admission and any missing information will be gathered by the principal investigator.

Progress: The original principal investigator, MAJ George Woodward, had too few patients to report any significant data. He graduated in June, and the study is continued with a new principal investigator.

# Detail Summary Sheet

Date: 19 Sep 90 Proj No: C-11-90 Status: Terminated  
 Title: The Utility of Single-Dose Gentamicin in Combination with Oral Trimethoprim-Sulfamethoxazole in the Outpatient Management of Pyelonephritis

Start Date 7 Dec 89	Est Comp Date:
Principal Investigator Stephen J. Perkins, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Dept. of Emergency Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To examine the effect of a single IV loading dose of gentamicin in combination with a standard oral regimen of trimethoprim-sulfamethoxazole (TMP/SMX) on reduction of the complication rate, subsequent need for hospitalization and relapse rate in a select group of patients (i.e. healthy adult women) with pyelonephritis treated as outpatient. In addition, as there are limited data on outpatient management of pyelonephritis in general, further information about the appropriateness of outpatient treatment should be generated. This may include clinical markers that indicate probable failure of outpatient treatment and the need for immediate hospitalization and extended intravenous antibiotic administration.

Technical Approach: 240 healthy adult females who meet clinical criteria for inclusion will be enrolled. Patients will be randomized to receive either a 2.0 mg/kg IV loading dose of gentamicin or placebo, discharged on oral TMP/SMX and their response to therapy followed based on clinical signs and symptoms, urine culture results, and need for subsequent hospitalization.

Progress: Study terminated due to lack of patients and PCS of principal investigator.

# Detail Summary Sheet

Date: 30 Jul 90 Proj No: C-12-90 Status: Completed  
 Title: Analysis of Patients Who Leave A Military Emergency Department without Being Seen or Against Medical Advice.

Start Date 2 Jan 90	Est Comp Date:
Principal Investigator	Facility
George P. Sassu, D.O., CPT MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Dept. of Emergency Medicine	
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): 1) Obtain social and demographic data of the patient subset (both pediatric and adult) leaving without being seen or AMA;

2) Identify contributing factors (e.g., long waits to be seen, delays in obtaining consults, X-rays, and lab work; psychosocial aspects);

3) Determine if LWBS or leaving AMA was detrimental to the patient; and

4) Recommend solutions that may improve patient care and improve utilization of hospital and ED resources.

Technical Approach: During the study period, 17,148 patients visited the Emergency Department. Of this number 110 patients (0.64%) left without being seen. Social and demographic data was collected on 91 who consented to a telephonic interview. The study group was matched for age, sex, time of presentation, and urgency of complaint against a control group that did not leave.

Progress: The data revealed patients who left did not wait longer to be seen than those who stayed, usually waited less than two hours before leaving, presented with minor complaints, and had resolution of their problem. Most left on the 3:00 P.M. to 11:00 P.M. shift, and the majority occurred on a Tuesday or Saturday. Almost one-half stated they waited too long to see a physician; this group of patients waited significantly longer before leaving than any other group. Differences in waiting times by age, sex, and marital status were not significant.

# Detail Summary Sheet

Date: 29 Nov 90 Proj No: C-34-90 Status: Ongoing  
 Title: Comparison of a New Pressurized Saline Cleaner Versus Syringe Irrigation of Traumatic Outpatient Laceration Cleansing.

Start Date 13 Feb 90	Est Comp Date:
Principal Investigator (vice Norris) Kevin Rodgers, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Samuel Coleridge, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): A multi-center prospective, randomized, nonblinded study to compare the safety and efficacy of the Dey-Wash Skin Wound Cleanser to traditional needle and syringe saline irrigation in cleansing outpatient lacerations.

Technical Approach: This will be a multi-center prospective, randomized, nonblinded study designed to compare the safety and efficacy of an aerosolized 0.9% sodium chloride solution ("Dey-Wash Skin Wound Cleanser") with a standard irrigation with 250 ml of normal saline using a 35 ml syringe and 20-gauge angiocath in cleansing traumatic, suturable lacerations in the emergency department. After cleansing, the wounds will be closed in a standard fashion. Wounds will be assessed at the time of suture removal (and any time the patient should present to the ED for wound check) for any sign of complications (infection, dehiscence, etc.).

Progress: Data continues to be collected regarding the efficacy of the Dey-Wash Skin Cleanser.

# Detail Summary Sheet

Date: 25 Sep 90 Proj No: C-41-90 Status: Ongoing  
 Title: Efficacy of Using Fresh Tampons in Menstruating Women to Obtain Adequate Midstream Clean-Catch Urine Specimens.

Start Date 12 Mar 90	Est Comp Date:
Principal Investigator Scott A. Crollard, CPT	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 25	
Total Number of Subjects Enrolled to Date: 25	
Date of Periodic Review	Results

Objective(s): To determine whether the use of a freshly inserted vaginal tampon can limit bloody contamination in midstream clean catch urine samples obtained in women with active menstruation or vaginal bleeding, and to compare the analysis of such samples to urine obtained via bladder catheterization.

Technical Approach: Approximately 40 women with active menstruation or vaginal bleeding will be needed for the study. The women will be randomized into two groups: 1) Midstream clean-catch (MSCC) urine with a vaginal tampon in place whereas the other half will perform a MSCC urine sample as normally instructed. Straight bladder catheterization (in and out) will then be performed by nurses using a sterile povidone iodophor prep and the disposable "Davol female cath kit."

Progress: No complications or new risks have been noted.

# Detail Summary Sheet

Date: 1 Oct 90 Proj No: C-47-90 Status: Ongoing  
 Title: Comparison of Verapamil and Adenosine for Treatment of Paroxysmal Supraventricular Tachycardia in the Emergency Department.

Start Date 27 Mar 90	Est Comp Date:
Principal Investigator Robert W. Wilson, CPT	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 8	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review	Results

Objective(s): a) Is there a difference in efficacy (as measured by rate of conversion to normal sinus rhythm) of the two agents (verapamil and adenosine) in the treatment of PSVT in the Emergency Department. b) Is there a difference in the number/significance of side effects (events requiring intervention or causing patient discomfort) between the two agents in the Emergency Department.

Technical Approach: Sixty subjects will be studied in a prospective, randomized, placebo controlled, double-blinded treatment protocol over a one year period. The rates of conversion to sinus rhythm and the incidence of side effects of the two agents will be measured and compared.

Progress: Of the eight patients entered, four have been given adenosine (A) and four have been given verapamil (V). For V 2 of 4 converted and for A 2 of 4 converted. No doses of normal saline (NS) converted the 6 patients who received NS. Side effects included: V - chest pain 1, mild hypotension 2; A- chest pain 2, shortness of breath 3, flushing 3, nausea 1, dizziness 1, other 4. All side effects were transient and none required intervention. Normal saline side effects were: flushing 1, shortness of breath 1, dizziness 1, diaphoretic 1, anxious 1, and nausea 1. A similar study has been approved at WHMC and should double the rate of patient entry.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-81-90 Status: Ongoing  
 Title: A Multicentric Randomized Study of the Comparative Efficacy of Penicillin VK versus Amoxicillin/Clavulanic Acid in the Prophylactic Treatment of Dog Bite

Start Date 2 Aug 90	Est Comp Date:
Principal Investigator Benjamin H. Walker, Jr., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To assess the relative efficacy of amoxicillin/clavulanic acid (Augmentin) versus penicillin VK in the prevention of infection after dog bites.

Technical Approach: Patients meeting the inclusion criteria who are victims of dog bites with full thickness wounds will be randomized to received either augmentin or penicillin VK. The physician treating the patient will fill out a form with the following information: age of patient, age of wound(s), number of wounds, location of wound(S), puncture or laceration, whether or not wound was closed. Patients will be asked to return in 48-72 hours. At that time wound(s) will be assessed for frank pus, lymphangitis, cellulitis, surrounding erythema greater than 1 mm, or increasing tenderness.

Progress: This is a new study. No reportable data are available at this time.

# Detail Summary Sheet

Date: 25 Oct 90 Proj No: C-105-90 Status: Ongoing  
 Title: Evaluation of Prophylactic Dicloxacillin in Cat Bite and Cat Scratch Wounds

Start Date 10 Oct 90	Est Comp Date:
Principal Investigator Robert W. Wilson, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine if prophylactic treatment of cat bite and cat scratch wounds with dicloxacillin reduces the rate of infection.

Technical Approach: The study population will consist of approximately 50 adult patients who have received cat bites and/or scratches less than four hours before presenting to the Emergency Department. The study will use a randomized, double-blinded protocol to compare treatment with dicloxacillin and placebo. All patients will be seen again 24 to 72 hours after initial presentation and will be called at home at the completion of the study. The percentages of infected wounds in the two groups will be compared using the chi-square test.

Progress: None. This is a new study.



# Detail Summary Sheet

Date: 25 Oct 90                      Proj No: C-106-90                      Status: Ongoing  
 Title: Clinical Evaluation of the Bullard Laryngoscope

Start Date 10 Oct 90	Est Comp Date:
Principal Investigator Robert W. Wilson, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To compare the clinical efficacy of the Bullard laryngoscope to standard laryngoscopes.

Technical Approach: Forty adult patients who die in the emergency department will be entered into the study after informed consent is obtained from the next-of-kin. Each patient will be intubated twice. One technique will be direct orotracheal intubation using in-line stabilization. The second technique will be using the Bullard technique. The Bullard laryngoscope is a new, indirect, fiberoptic laryngoscope. Data collected will include time to visualization of cords, time to intubation, number of attempts and complications.

Progress: This is a new study.

# Detail Summary Sheet

Date: 18 Sep 90 Proj No: C-51-83 Status: Ongoing  
 Title: Use of Isotretinoin in Prevention of Basal Cell Carcinoma.

Start Date 16 Jun 83	Est Comp Date:
Principal Investigator (vice Salasche) William J. Grabski, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators: Catherine Pollard, R.N. Martha McCullough, MAJ, MC
Key Words: Basal cell carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date: 168	
Date of Periodic Review n/a	Results Open for Follow-Up

Objective(s): To evaluate the effectiveness of low dosage levels of isotretinoin in reducing the incidence of basal cell carcinomas in a high risk population; to examine possible side effects associated with long term administration of low doses of isotretinoin.

Technical Approach: Patients having at least two basal cell carcinomas in the last five years are contacted. If interested in participation, they are screened according to protocol. If all inclusion factors are met, they are randomized and begun on medication or placebo. After beginning medication, follow-up will occur at two weeks, three months, six months and every six months thereafter for the duration of the study. Patients are on medication for three years and have follow-up for two years afterward. Physical exams are done at the baseline and 36 month visits. History, total skin exam, and necessary biopsies are done at each visit. Laboratory data is collected at the 2 week, 3 month, 6 month, 12 month, 24 month and 36 month visit. Lateral cervical and thoracic spine films are done at 0 and 36 month visit at this point in the study.

Progress: At present, the number of patients participating in this study is split between those still in the 4 year course of the study and those continuing to be followed post study. To date, 78 patients are actively participating in the study. Of the 169 patients enrolled, 9 have died, 6 have moved from the study site and 5 have left the study for conflicting health reasons. As of June 1990, all patients completed their 3 year medication trial period. These patients were individually notified in July 1990 as to whether they were taking Isotretinoin or the placebo. No laboratory data nor x-rays are required since all patients are off medication. Seventy-one patients continue to be followed post study for tumor recurrences.

# Detail Summary Sheet

Date: 29 Nov 90 Proj No: C-18-84 Status: Completed  
 Title: Congestive Cardiomyopathy: Evaluation of Transvenous Myocardial Biopsy and Treatment with an Anti-Inflammatory Regimen.

Start Date 16 Mar 84	Est Comp Date:
Principal Investigator Ricky D. Latham, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators:
Key Words: Cardiomyopathy, congestive	Bernard J. Rubal, Ph.D. Renu Virmani, MAJ, MC, AFIP Max Rabinowitz, M.D., AFIP James Baker, M.D., WRAMC Stephen Ramee, CPT, MC, LAMC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$3373.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 12 Mar 90	Results Continue

Objective(s): To assess the efficacy of using an endomyocardial biopsy technique in the diagnosis and management of congestive cardiomyopathy by identifying specific etiologies and/or those patients with an inflammatory cellular reaction.

Technical Approach: Patients undergo complete noninvasive assessment with laboratory echocardiogram, MUGA, and Gallium. Then, if eligible, endomyocardial biopsy is performed. NIH interprets the histology and Hahnemann University does immunological assessment. Patients must have cath proven normal coronary arteries. Patients should be randomized to Prednisone and noninvasive studies repeated in 6 months, 12 months, and 18 months.

Protocol has been amended to include left heart biopsy.

Progress: The principal investigator reported "Study completed; published April 1990." However, neither the manuscript nor a summarization of the results are available.

# Detail Summary Sheet

Date: 29 Nov 90 Proj No: C-19-84 Status: Completed  
 Title: Dipyridamole MUGA Studies Compared with Quantitative Tomographic Stress and Dipyridamole Infusion TL201 Scintigrams for Assessing Coronary Artery Disease.

Start Date 16 Mar 84	Est Comp Date:
Principal Investigator Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Michael Cawthon, MAJ, MC James Gilman, LTC, MC Joseph P. Murgo, M.D.
Key Words: Coronary artery disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 6	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review 12 Mar 90	Results Continue

Objective(s): To assess the sensitivity of dipyridamole MUGA study as compared to dipyridamole infusion TL 201 studies to detect significant coronary artery disease.

Technical Approach: IV Persantine, 60 mg/kg, is given over 4 minutes. TL<sup>201</sup> is given 2 minutes after infusion. For MUGA, TCM<sup>99</sup> is given and rest study performed before infusion. Studies are then done at 3 minute intervals x 4. All patients are submitted to cardiac catheterization and results of anatomy are determined.

Phase II approach changed and approved by IRB to use ventriculography instead of DSA.

Progress: Following reporting this study as having been completed in the FY-89 Annual Research Progress Report, the principal investigator requested that it remain open in order to study additional patients with dipyridamole. Six additional patients were enrolled, and there was no change in previous results. Ventriculograms revealed no specific changes and IV MUGA was 63% sensitive.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-60-86 Status: Ongoing  
 Title: The Natural History of HTLV-III Infection and Disease in a United States Military Population.

Start Date 25 Jun 86	Est Comp Date:
Principal Investigator C. Kenneth McAllister, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators:
Key Words: HTLV-III	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date: 300	
Date of Periodic Review n/a	Results

Objective(s): 1) To assess the impact of HTLV-III infection on fitness for duty (deployability, military readiness and retention) by systematically defining the natural disease progression in individuals with documented HTLV-III infections in the general military population (active duty, dependents and retirees).

2) To form an information basis and a study cohort upon which number other studies can be built (i.e., drug treatment of HTLV-III, etc.)

Technical Approach: Each HTLV-III infected individual will be staged according to the Walter Reed Staging Classification. The only additional requirements of individuals enrolled in this study are (1) additional information gathered from each individual as a consequence of this study will be centralized in a common data base; (2) serum and CSF will be stored at WRAIR for future testing.

Progress: Tabulation of demographic data which is centralized on WRAIR computers continues.

# Detail Summary Sheet

Date: 20 Aug 90                      Proj No: C-74-86                      Status: Terminated  
 Title: Intensive Chemotherapy, Delayed Local Irradiation, Total Body  
 Irradiation and Autologous Bone Marrow Rescue in Treating High Risk Ewing's  
 Sarcoma

Start Date 12 Aug 86	Est Comp Date:
Principal Investigator Richard O. Giudice, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Timothy J. O'Rourke, LTC, MC Paul J. Thomas, COL, MC Barbara Reeb, GS-9
Key Words: Sarcoma, Ewing's	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 12 Sep 90	Results Terminated

Objective(s): 1) To improve disease-free survival of patients with Ewing's sarcoma having a high risk of treatment failure.

2) To test the effectiveness of intensive inducition chemotherapy, delayed RT to the primary tumor and TBI with ABMR.

3) To test the toxicity of such a regimen.

4) To test the accuracy of currently available staging techniques and monitoring techniques in recognizing residual primary and metastatic tumor.

5) To test whether tumor size independently of other variables predicts long-term disease-free survival.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: One patient enrolled on study. No new patients have been enrolled in the past two years. Therefore, the study is terminated due to the rarity paucity of eligible participants.

# Detail Summary Sheet

Date: 17 Oct 90 Proj No: C-2-87 Status: Ongoing  
 Title: Percutaneous Transluminal Valvuloplasty in Adult Mitral/Aortic Stenosis

Start Date 19 Nov 87	Est Comp Date:
Principal Investigator (vice Bailey) W. Randy Condos, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators:
Key Words: Stenosis, aortic Stenosis, mitral	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review 29 Jan 90	Results Continue

Objective(s): To apply the technique of percutaneous balloon dilatation of valvular aortic/mitral stenosis to a patient population at high risk of morbidity and mortality from aortic/mitral valve replacement and/or chronic anticoagulation.

Technical Approach: All patients age 21 or older with hemodynamically proven symptomatic aortic stenosis of either calcific/degenerative or congenital etiologies or patients age 21 or older with hemodynamically proven, significant mitral valve stenosis will be eligible if they are clinically considered to be a high risk for surgical valve replacement or chronic anticoagulation. Cardiac catheterization and valvuloplasty will be performed as outlined in the study protocol.

Progress: Six patients have been enrolled to date. Study still in progress.

# Detail Summary Sheet

Date: 15 Mar 90 Proj No: C-13-87 Status: Terminated  
 Title: Evaluation of Biventricular Performance in the Deinnervated Heart

Start Date 15 Jan 87	Est Comp Date:
Principal Investigator Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Steven R. Bailey, MAJ, MC Ares Pasipoularides, M.D., Ph.D.
Key Words: Heart, deinnervated	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 12 Mar 90 Results Terminated	

Objective(s): To examine the following biventricular parameters in the deinner-  
 vated heart at rest, volume expansion (leg raising) and submaximal dynamic exer-  
 cise: (1) systolic ejection indices; (2) pressure volume loops; (3) diastolic  
 indices of stress-strain; and (4) hemodynamic response to Valsalva and Mueller  
 maneuvers.

Technical Approach: To evaluate the exercise (E) response in cardiac transplant  
 (Tx) patients (pts) on cyclosporine, we performed right and left heart cathe-  
 terization at rest (R) and supine bicycle (E) using multisensor high fidelity  
 catheters. Four pts (3 females, 1 male) mean age 47+15 years, mean 10+months  
 post transplant, who were clinically stable and free of rejection by biopsy were  
 studied off cardiac medications.

High fidelity catheters were used to measure simultaneous aortic root pressure  
 (Ao) and flow velocity and LV pressure at rest and during supine bicycle exer-  
 cise (Ex). Fourier analysis of Ao and flow signals was used to calculate  
 characteristic input impedance ( $Z_c$ ). Diastolic decay Ao was used to determine  
 systemic compliance (C) by a monoexponential model (RC).

Progress: This study was terminated because evaluation of biventricular perfor-  
 mance is standard follow-up procedure for heart transplant patients.



# Detail Summary Sheet

Date: 25 Oct 90 Proj No: C-42-87 Status: Completed  
 Title: Total Systemic and Regional Aortic Compliance at Rest and with Exercise

Start Date 9 Apr 87	Est Comp Date:
Principal Investigator David Slife, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Ricky D. Latham, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 10	
Date of Periodic Review 14 May 90 Results Continue	

Objective(s): 1) To compare compliance as determined by a three-element windkessel arterial model (using aortic input pressure and flow) at rest and with exercise, to compliance determined by the standard RC model in normal man.

2) To compare aortic compliance by each method in normal and hypertensive patients.

3) To evaluate the regional proximal aortic contribution to the total systemic capacitance.

Technical Approach: We measured simultaneous pulmonary artery pressure and flow with a multisensor micromanometer flow velocity catheter during routine cardiac catheterization in ten normal subjects to evaluate the parameters of the three-element Windkessel model: pulmonary characteristic impedance ( $Z_c$ ), pulmonary vascular resistance (PVR) and pulmonary arterial compliance ( $c_p$ ). These values were then compared to independent calculations of these variables.

Progress: This was the first use of the three-element Windkessel model to describe pulmonary vascular dynamics in man. We found that the parameter estimates were appropriate both at rest and exercise. Given these findings and excellent correlations with normalized (to body weight) values in other species, the compliance value from the three-element Windkessel model is a good estimate of the true value when the correlation of model to measure is  $R > 0.90$ .

# Detail Summary Sheet

Date: 18 Sep 90	Proj No: C-52-87	Status: Ongoing
Title: Autologous Bone Marrow Rescue in Patients with Acute Leukemia and Lymphoma Using Ex-Vivo Marrow Treatment with 4-Hydroperoxycyclophosphamide (4-HC)		
Start Date 13 May 87	Est Comp Date:	
Principal Investigator Svetislava J. Vukelja, MAJ, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Terry E. Pick, COL, MC Allen Potter, LTC, MC Barbara Reeb, DAC Rory Duncan, SGT Robert G. Whiddon, Jr., LTC, MS	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: _____		
Total Number of Subjects Enrolled to Date: 14		
Date of Periodic Review 14 May 90 Results Continue		

Objective(s): 1) To evaluate autologous marrow rescue after intensive therapy in patients with acute leukemia and lymphoma in second remission or subsequent remission or in early relapse.

2) To study the effects of ex-vivo bone marrow purging utilizing 4-HC on malignant cells, marrow stem cells, and relationship to subsequent engraftment times.

3) To study the acute toxic effects of the preparative regimens.

Technical Approach: To be eligible for this study, all patients must have a diagnosis of acute leukemia or aggressive histology lymphoma and have relapsed after therapy. Bone marrow should be harvested when the patient is in remission.

Therapy will follow the schema outlined in the study protocol.

Progress: Although 14 patients have had marrow purging, only 2 have had re-infusion. Both are doing well.

# Detail Summary Sheet

Date: 26 Sep 90      Proj No: C-59-87      Status: Ongoing  
 Title: Phase I Study of LY188011 (Difluorodeoxycytidine)

Start Date 29 May 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 8 (30)*	
Total Number of Subjects Enrolled to Date: 8 (30)*	
Date of Periodic Review 14 May 90	Results Continue

Objective(s): To determine the maximum tolerated dose of LY188011 as a single dose given for 5 consecutive days with each cycle repeated every 21 days.

Technical Approach: Patients must have a microscopically confirmed diagnosis of metastatic or advanced cancer. Patients' cancers must be refractory to effective therapy (surgery, radiotherapy, chemotherapy) as well as other investigational agents of higher potential efficacy. Patients must have a predicted life expectancy of at least 12 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: The numbers reported above indicate only those patients entered on the every two weeks schedule instituted in August 1989 for this joint BAMC/UTHSC project. This study is on the verge of completion with the maximum tolerated dose to date 2500 mg/m<sup>2</sup>. The major toxicity to date is myelosuppression which is expected to be dose limiting.

# Detail Summary Sheet

Date: 20 Aug 90 Proj No: C-62-87 Status: Ongoing  
 Title: Development of an Autologous Bone Marrow Rescue Program (Master Protocol)

Start Date 25 Jun 87	Est Comp Date:
Principal Investigator (vice Giudice) Svetislava J. Vukelja, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Paul J. Thomas, COL, MC Allen Potter, LTC, MC Robert G. Whiddon, Jr., LTC MS Barbara Reeb, DAC Rory Duncan, SGT
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 11,595.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 21	
Date of Periodic Review _____	Results _____

Objective(s): 1) To develop an autologous bone marrow rescue program at Brooke Army Medical Center.

2) To participate in research and clinical studies individually as well as part of the Southwest Oncology Group and Pediatric Oncology Group.

3) To establish a competent marrow rescue service for all eligible DOD patients for present clinical indications and future indications, i.e., radiation exposure.

Technical Approach: Bone marrow stem cells will be obtained by multiple bone marrow aspirations under general anesthesia. The marrow will be prepared by accepted methods and frozen for future reinfusion.

This is the master protocol for the autologous bone marrow transplant program.

Progress: Twenty-one patients have been harvested of which 11 were adults and 10 were pediatric cases. Five of the pediatric and five of the adult patients underwent autologous bone marrow transplantation.

# Detail Summary Sheet

Date: 20 Aug 90		Proj No: C-64-87		Status: Ongoing	
Title: Evaluation of Patients with Human Immunodeficiency Virus (HIV) Seropositivity Detected by Screening for the Presence and Potential Etiology of Exercise Intolerance					
Start Date 2 Jul 87			Est Comp Date:		
Principal Investigator James E. Johnson, MAJ, MC			Facility Brooke Army Medical Center		
Dept/Svc Department of Medicine/Pulmonary			Associate Investigators: Gregg T. Anders, MAJ, MC Herman M. Blanton, MAJ, MC Eleanor Ayala, DAC		
Key Words:					
Accumulative MEDCASE Cost:			Est Accumulative OMA Cost:		
Number of Subjects Enrolled During Reporting Period: _____					
Total Number of Subjects Enrolled to Date: 40					
Date of Periodic Review 12 Sep 90 Results Continue					

Objective(s): Patients with HIV seropositivity have been noted to have exercise intolerance at an early stage when they are otherwise asymptomatic. The goals of this study are as follows: 1) To determine the prevalence of complaints of exercise intolerance and dyspnea in the study population. 2) To document whether abnormalities of exercise physiology exist in these patients complaining of exercise intolerance. 3) To evaluate these patients for potential causes of exercise intolerance such as early opportunistic pulmonary infection or lymphocytic interstitial pneumonitis (LIP).

Technical Approach: All active duty patients admitted to the HIV ward or referred to the HIV clinic for evaluation will be considered eligible for the study. These patients will be given a questionnaire on the day of admission including questions regarding exercise tolerance and dyspnea as well as previous lung, heart and muscle diseases. The response to these questions will be used for further patient selection. All participants will undergo gallium scan of the lungs, pulmonary function testing to include lung volumes and a DLCO, cycle ergometry pulmonary exercise testing and bronchoalveolar lavage (BAL). The BAL fluid will be divided and submitted for the following: 1) staining for routine cytological evaluation (for evidence of viral infection) as well as for AFB and GMS stains; 2) culture for AFB, Fungi, CMV and HIV virus; 3) HIV antigen testing for comparison to peripheral blood titers; 4) quantitation of lymphocytes, PMN's, monocytes as well as lymphocyte subsets particularly OKT4 and OKT8.

Progress: To confirm the presence of exercise dysfunction in patients seropositive for the HIV, 32 such patients without AIDS were evaluated with cardio-pulmonary exercise testing, pulmonary function testing, bronchoalveolar lavage,

C-64-87 (Continued)

chest roentgenography, and gallium scanning. No evidence of pulmonary opportunistic infection was found. When compared to an otherwise similar group of HIV-seronegative controls, the patients exercised to a significantly lower workload ( $195 \pm 30$  versus  $227 \pm 31$  W,  $p < 0.001$ ). The ventilatory anaerobic threshold (VAT) values were also significantly lower for the patients ( $49.2 \pm 13.0$  versus  $61.9 \pm 9.1\%$  of maximum predicted  $\text{Vo}_2$ ,  $p < 0.001$ ). Nine of the patients had VAT values less than the 95% confidence interval for the controls. This subgroup exercised to a significantly lower maximum  $\text{Vo}_2$  ( $69.9 \pm 11.2$  versus  $95.9 \pm 17.5\%$  of maximum predicted  $\text{Vo}_2$ ,  $p < 0.001$ ) and workload ( $164 \pm 21$  versus  $227 \pm 31$  W) when compared to the control group. These patients demonstrated a mild tachypnea throughout exercise relative to the controls and had a significant increase in the slope of the heart rate to  $\text{Vo}_2$  relationship. These findings are most consistent with a limitation of oxygen delivery to exercising muscles, which may represent occult cardiac disease in this group.

Publications:

Johnson, J.E., Ander, G.T., Blanton, H.M., et al. Exercise dysfunction in patients seropositive for the human immunodeficiency virus. *Am Rev Respir Dis* 141:618-622, 1990

Johnson, J.E., Anders, G.T., Hawkes, C.E., et al. Bronchoalveolar lavage findings in patients seropositive for the human immunodeficiency virus (HIV). *Chest* 97:1066-1071, 1990.

Anders, G.T., Timmons, J.H., Johnson, J.E., et al. SPECT Gallium-67 scanning in early human immunodeficiency virus (HIV) infection - Failure of scanning abnormalities to correlate with immunologic staging. *Clin Nuc Med* 15(5):295-302, 1990.

# Detail Summary Sheet

Date: 2 Aug 90 Proj No: C-66-87 Status: Ongoing  
 Title: Immunosuppressive Therapy for Biopsy Proven Myocarditis (Collaborative Study with University of Utah Medical Center and Centers for Multicenter Trial)

Start Date 2 Jul 87	Est Comp Date:
Principal Investigator Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: William R. Condos, LTC, MC
Key Words: Myocarditis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 13 Aug 90 Results Continue	

Objective(s): To test the hypothesis that immunosuppressive therapy is beneficial in myocarditis.

Technical Approach: This is a national multicenter trial including 23 patient enrollment centers. Therapy will follow the schema outlined in the study protocol.

Progress: Patient enrollment has been completed. Data are being analyzed.

# Detail Summary Sheet

Date: 2 Aug 90 Proj No: C-70-87 Status: Completed  
 Title: High Dose Busulfan with Autologous Bone Marrow Rescue

Start Date 17 Jul 87	Est Comp Date:
Principal Investigator (vice Giudice) Svetislava J. Vukelja, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: R. Foulke, MAJ, MC Paul Thomas, COL, MC Allen Potter, LTC, MC Barbara Reeb, DAC Rory Duncan, SGT Robert G. Whiddon, Jr., LTC, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 6500.00
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 17	
Date of Periodic Review 5 Apr 90	Results Continue

Objective(s): 1) To study the toxicities associated with the treatment of refractory malignancies, utilizing cyclophosphamide, busulfan and etoposide.

2) To evaluate the response rates and the response duration of patients treated with the above regimen.

Technical Approach: An IND for busulfan was obtained in March 1987. The protocol was amended in June to include the use of cyclophosphamide and etoposide (VP-16). Inclusion/Exclusion criteria and therapy is as outlined in the study protocol.

Progress: Since the last report, four patients with metastatic breast cancer have been enrolled in the study. One is in complete remission, one is in partial remission, and one has progressive disease.

It has been opted to discontinue use of the investigational drug, busulfan (IND 29,887). A new protocol has been approved in which the commercially available busulfan will be used in the treatment of metastatic breast cancer.



# Detail Summary Sheet

Date: 6 Sep 90 Proj No: C-71-87 Status: Terminated  
 Title: Use of Clofazimine in Immunocompromised Patients for the Treatment of Infections Caused by Mycobacterium Avium-Intracellulare and Other Atypical Mycobacteria Resistant to Conventional Antituberculous Therapy.

Start Date 17 Jul 87	Est Comp Date:
Principal Investigator J. William Kelly, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review 10 Sep909	Results Terminate

Objective(s): To use and determine the effectiveness of the investigaitonal drug clofazimine (Lamprene®) for the treatment of infections due to Mycobacterium avium-intracellulare and other atypical mycobacteria in immuno-compromised patients.

Technical Approach: Selection of patients will be on the basis of medical history, physical examination and laboratory studies including an evaluation of immunological status. Attempts will be made to culture body fluids and or tissue specimens from patients to substantiate the presence of atypical mycobacterial infection. All mycobacterial isolates will be tested in vitro for sensitivity to clofazimine.

Progress: Since last review clofazimine has been released by the FDA to the open market. Therefore, we recommend that the study be terminated.

# Detail Summary Sheet

Date: 6 Aug 90 Proj No: C-72-87 Status: Terminated  
 Title: Rifabutin (Ansamycin LM 427) CDC Protocol

Start Date 17 Jul 87	Est Comp Date:
Principal Investigator J. William Kelly, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 10 Sep 90 Results Terminate	

Objective(s): To determine the effectiveness of Rifabutin in the treatment of patients with disseminated M. avium complex disease, localized M. avium complex disease unresponsive to standard therapy, selected patients with rifampin-resistant M. tuberculosis, and other selected patients with mycobacterial infections.

Technical Approach: Under the compassionate release IND, Rifabutin is intended for immunocompromised patients with disseminated M. avium complex disease, patients with pulmonary MAC disease unresponsive to standard therapy, and patients with rifampin-resistant tuberculosis. Other patients with mycobacterial diseases which have not responded to standard therapy may also be eligible to receive Rifabutin. Therapy will follow the schema outlined in the study protocol.

Progress: This study was terminated by the Center for Disease Control.

# Detail Summary Sheet

Date: 20 Aug 90 Proj No: C-88-87 Status: Completed  
 Title: A Survey of Intracolonic Combustible Gas Compositions with Various Endoscopic Preparations

Start Date 10 Sep 87	Est Comp Date:
Principal Investigator David Monahan, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Fred Goldner, COL, MC
Key Words: Gas, intracolonic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 573.50
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): 1) To determine whether phosphate enema is an adequate preparation for rectosigmoid electrocautery during sigmoidoscopy, with respect to concentrations of combustible gases.

2) To determine how an oral polyethylene glycol preparation (Colyte, Edlaw Preparations) and phosphate enema (C.B. Fleet Co.) compare with respect to combustible gas concentrations in the rectum.

3) To determine how regional concentrations of combustible gases in the colon correlate with regional visual assessments of bowel preparation with polyethylene glycol.

Technical Approach: Thirty patients undergoing routine flexible sigmoidoscopy and thirty patients undergoing routine colonoscopy were evaluated. The standard bowel cleansing regimens for each procedure were utilized. At colonoscopy, six gas samples were obtained via a polyvinyl tube passed through the scope. The method of collecting gas samples during flexible sigmoidoscopy was identical.

Progress: After air insufflation during colonoscopy, the concentrations of hydrogen and methane remained below combustible levels in all patients. However, during flexible sigmoidoscopy, 3/30 or 10% of patients developed combustible levels of either hydrogen or methane in their colon. This persisted even after air insufflation. This offers an explanation for multiple reports of explosions in the bowel during electrocautery. Our results suggest that electrocautery carries an increased risk of explosion during flexible sigmoidoscopy. Therefore, electrocautery should only be performed during colonoscopy after full bowel preparation.

# Detail Summary Sheet

Date: 20 Sep 90      Proj No: C-11-88      Status: Ongoing  
 Title: Effect of Thyroid Replacement on Lipid Profile - Differences Associated with Keeping the TSH in Low Normal as Compared to Upper Normal Euthyroid Range

Start Date 2 Dec 87	Est Comp Date:
Principal Investigator Albert M. Thomason, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Endocrinology	Associate Investigators:
Key Words: Euthyroid	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 29 Jan 90	Results Continue

Objective(s): To demonstrate a difference in the lipid profile of euthyroid patients treated with higher or lower doses of thyroid replacement therapy.

Technical Approach: Patients being treated with thyroid replacement would be enlisted as volunteers. Individual patients would have their TSH levels adjusted by varying their thyroid replacement dose to above 3.5 mcIU or below 1.1 mcIU/ml depending on whether the initial value was above or below the mean euthyroid value of 2.3 mdIU/ml. The patient would be maintained at the lower or higher TSH value for 3 months as determined by monthly measurements. Then, the patient's serum lipid profile (cholesterol, triglyceride, and HDL cholesterol) would be determined after a 14 hour fast x 2. Subsequently, the patient would have his dosage of thyroid replacement adjusted to keep his TSH value in the opposite end of the euthyroid range from which it was initially. After three months of stabilization of the new value of TSH level, the plasma lipid profile would be repeated. Subsequently, the patient would once again have his TSH value adjusted to a relatively higher or lower value depending on where he started initially. After another 3 month period of stabilization, lipid profile would again be obtained.

Progress: Of the five patients who began this study, only one has completed it. Would like to keep the study open for one more year.

# Detail Summary Sheet

Date: 9 Oct 90 Proj No: C-17-88 Status: Terminated  
 Title: Evaluation of Immunocyte Populations in Mice Infected with Coccidioides immitis (fungus)

Start Date 16 Dec 87	Est Comp Date:
Principal Investigator J. William Kelly, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: David L. Danley, MAJ, MS Rebecca Cox, Ph.D. Janice M. Grassel, M.T.
Key Words: <u>Coccidioides immitis</u>	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To evaluate, using flow cytometry, the immunocyte populations associated with Tissues infected with C. immitis from susceptible and resistant strains of mice.

Technical Approach: In this study we propose to identify and enumerate different immunocyte populations in the spleen and peripheral blood of DBA/2 and BALB/c mice infected intranasally with C. immitis, using a fluorescence-activated cell sorter (FACS). All animals will be maintained and infected by Dr. R. Cox and her associates at the San Antonio Chest Hospital. Animals will be infected with ten spores intranasally. At various times after infection, spleen cells, peripheral blood, and lung tissue will be recovered. A single cell suspension will be obtained from solid tissue by mincing the organs in balanced salt solution; whereas peripheral leukocytes will be assayed without separation from contaminating erythrocytes.

Progress: Study terminated due to time constraints.

# Detail Summary Sheet

Date: 20 Sep 90 Proj No: C-19-88 Status: Ongoing  
 Title: Effect of Oral Agents vs Insulin Therapy on Lipid Profile

Start Date 13 Jan 88	Est Comp Date:
Principal Investigator Albert M. Thomason, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Endocrinology	Associate Investigators:
Key Words: Insulin therapy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 Mar 90	Results Continue

Objective(s): To demonstrate whether low density lipoprotein cholesterol and total cholesterol-high density lipoprotein cholesterol ratios are worse in Type II diabetics treated with insulin as compared to oral agents.

Technical Approach: 30 patients being treated with oral hypoglycemic agents would be enlisted as volunteers. For the first 3 months, the patient would be followed on his/her usual oral hypoglycemic agent to determine average HGB A1C and lipid profile values. Subsequently the patient would be taken off the oral hypoglycemic agent and placed on human insulin therapy in such a dosage as to keep the Hgb A1C value as near as possible to the value the patient had while being treated with oral hypoglycemic agent. After 4 months on insulin therapy, the patient's lipid profiles for the previous 3 months would be averaged to compare the lipid profile while on oral hypoglycemic therapy. Subsequently, the patient would be taken off insulin and restarted on the same dose of hypoglycemic agent as previously taken. At the end of 4 months, the patient's lipid profile would be averaged as before.

Progress: Patients who volunteered for the study did not meet the inclusion criteria. Would like to keep the study open for one more year.

# Detail Summary Sheet

Date: 18 Sep 90	Proj No: C-37-88	Status: Ongoing
Title: A Comparison of Cine and DSA Quantitative Coronary Angiography		

Start Date 7 Mar 88	Est Comp Date:
Principal Investigator Lee B. Padove, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/General Medicine	Associate Investigators: Steven R. Bailey, MAJ, MC Eleanor Ayala, M.T., MBA
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To compare the latest automated techniques for evaluation of coronary artery stenoses to planimetry of coronary artery casts.

Technical Approach: With the consent of family members, ten cadavers wer studied. Hearts were removed and arteries selectively injected with barium latex at 10 ATM for five minutes. Biplane cineangiographic films plus digital images taken, coronary casts decalcified and sectioned.

This study has been amended to include the injection of the left and right ventricle with barium latex in order to get radiopaque casts. These casts are to be used in validation and comparison of ventriculography by DSA and cineangiography.

Progress: This study had previously been put on hold due to inability to obtain cast material. At that point six hearts had been obtained. The material has been received and plans are to use animal hearts in addition to human hearts to expedite completion.

# Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-47-88 Status: Ongoing  
 Title: Percutaneous Recanalization of Human Coronary Arteries with Balloon-Expandable Intracoronary Grafts (BEIG)

Start Date 25 Apr 88	Est Comp Date:
Principal Investigator W. Randy Condos, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 9	
Date of Periodic Review 13 Aug 90 Results Continue	

Objective(s): 1) To determine the safety of the stent by evaluating reported clinical complications associated with its placement.

2) To determine the effectiveness of the stent by evaluating patients for long-term patency rates. Patency will be compared with results reported in the literature for PTCA alone. In addition, results will be compared with follow-up of a concomitant group of control patients treated by PTCA.

Technical Approach: This study is designed as a prospective survey following placement of a Balloon Expandable Intracoronary Stent in a coronary artery. The stent will initially be implanted in patients with confirmed collateral blood flow to the distal portion of the stenotic coronary artery.

Progress: Fourteen stents were implanted in nine patients as part of the Phase I FDA trial, which closed about six months ago. We are awaiting FDA approval to participate in the Phase II study.



# Detail Summary Sheet

Date: 18 Sep 90 Proj No: C-71-88 Status: Terminated  
 Title: Evaluation of the Effects of Coronary Collateral Vessels on  
 Exercise-Induced Wall Motion Abnormalities

Start Date 5 Aug 88	Est Comp Date:
Principal Investigator Joseph P. Johns, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the role that the degree of coronary collateraliza-  
 tion has on the induction of exercise-induced wall motion abnormalities during  
 exercise echocardiography.

Technical Approach: Subjects will be recruited from patients at BAMC, and the  
 Audie Murphy VA Hospital, who have recently undergone cardiac catheterization  
 and selective coronary cineangiography for the investigation of known or  
 suspected coronary artery disease. When possible, all antianginal medications  
 will be discontinued three half-lives prior to exercise testing. Upright  
 bicycle exercise which allows for continuous echocardiographic imaging  
 throughout exercise and during recovery will be used. All exercise echocar-  
 diographic studies will be recorded on videotape for analysis.

Progress: This study was terminated due to lack of sufficient subjects and lack  
 of time allowed for research.

# Detail Summary Sheet

Date: 16 Oct 90 Proj No: C-74-88 Status: Terminated  
 Title: A Prospective Analysis of Cardiac Changes Related to Radiation Therapy

Start Date 5 Aug 88	Est Comp Date:
Principal Investigator William T. Wright, Jr., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: J. Mark Moody, LTC, MC Douglas Jackson, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To assess immediate (short term) effects of mediastinal irradiation on ventricular function.

2) To assess predictors of ventricular function before and after mediastinal irradiation.

3) To establish a baseline for evaluation of late cardiac changes, to include coronary artery occlusion related to radiation.

Technical Approach: Patients will be eligible for this study who are 18 years of age or older and who are to receive irradiation to the mediastinum including any portion of the heart in the field regardless of tumor type. Patients will be stratified to one of three groups according to the amount of heart included in the radiation field receiving a minimum of 1,000 rads. Groups in which less than or equal to one-third of total heart tissue, greater than one-third, but less than two-thirds of total heart tissue, and greater than two-thirds of total heart tissue will be identified. All patients will answer a symptom questionnaire prior to initiation of testing.

Progress: This study was terminated due to inability to obtain an adequate number of study subjects.

# Detail Summary Sheet

Date: 22 Aug 90	Proj No: C-78-88	Status: Ongoing
Title: Phase II Study of Patients with Primary Malignant Gliomas Treated with Intracranial Recombinant IL-2 and Autologous LAK Cells (Collaborative Study with Audie Murphy VA Hospital)		
Start Date 8 Sep 88	Est Comp Date:	
Principal Investigator	Facility	
Timothy J. O'Rourke, LTC, MC	Brooke Army Medical Center	
Dept/Svc	Associate Investigators:	
Department of Medicine/Oncology	Arlene J. Zaloznik, LTC, MC	
Key Words:	Mark R. Keaton, CPT, MC	
Glioma	Thomas D. Brown, M.D.	
Recombinant IL-2		
Accumulative MEDCASE	Est Accumulative	
Cost:	OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 1		
Total Number of Subjects Enrolled to Date: 1		
Date of Periodic Review 12 Sep 90 Results Continue		

Objective(s): 1) To determine the time of disease progression and overall survival in patients with primary malignant gliomas treated with surgical resection and postoperative intracranial IL-2 and autologous LAK cells.

2) To detect preliminary evidence for objective response in those patients with measurable disease postoperatively.

3) To determine the toxicity of IL-2 and autologous LAK cells administered intracranially in this patient population.

4) To correlate in vitro biologic parameters of these patients' malignant gliomas with their clinical outcomes.

Technical Approach: Patient eligibility and therapy is as outlined in the study protocol.

Progress: One patient has been entered on study. This patient tolerated two treatments well but appears to have progressed requiring radiation therapy. This course was also complicated by an infection of his Ommaya Reservoir that was successfully treated.

# Detail Summary Sheet

Date: 22 Aug 90 Proj No: C-88-88 Status: Completed  
 Title: Phase I Study of LY186641 (Sulfonylurea) Given Over 21 Days Every Four Weeks

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Hematology-Oncology Staff
Key Words: Sulfonylurea	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 12	
Date of Periodic Review 12 Sep 90 Results Completed	

Objective(s): To determine the maximum tolerated dose of LY186641 as single daily doses given in multiple courses of 21 consecutive days followed by a rest period of approximately 7 days.

Technical Approach: All patients must have a histopathologically confirmed diagnosis of advanced or metastatic cancer. Therapy will follow the schema outlined in the company protocol.

Progress: Four additional patients have been entered on study since the last report. The study is now closed, and all patients are off treatment. The maximum tolerated dose has been determined. The dose limiting toxicity is methemoglobinemia and hemolytic anemia. No unusual toxicities or severe toxicities have been seen.

# Detail Summary Sheet

Date: 3 Apr 90 Proj No: C-89-88 Status: Terminated  
 Title: A Randomized, Double-Blind Efficacy, Safety and Pharmacokinetic Study of Two Doses BMY-25801 in Patients Receiving High-Dose Cisplatin, Phase II

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator Terry R. Jenkins, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 3 Apr 90	Results Terminate

Objective(s): To compare the antiemetic efficacy, safety, and pharmacokinetics of two doses of BMY-25801 in 80 chemotherapy-naive cancer patients receiving cisplatin  $\geq 100$  mg/m<sup>2</sup> in combination with other chemotherapeutic agents.

Technical Approach: This is a randomized double-blinded parallel phase II trial comparing the antiemetic properties of two intravenous doses of BMY-25801, 1.2 mg/kg and 6.0 mg/kg, in 80 chemotherapy-naive cancer patients treated with cisplatin or in combination with other chemotherapeutic agents. Patients will be randomly allocated to receive 3 intravenous doses of BMY-25801 at 1.2 mg/kg or 6.0 mg/kg. The study will be administered over 15 minutes; 0.5 hours before and 1.5 and 3.5 hours after the initiation of the cisplatin infusion.

Progress: Based upon results from our trial and others, the compound was found to have clinical efficacy, but side effects consisting of hypotension and QT prolongation were also seen at higher doses. No clinically significant side effects were encountered at BAMC. Because of steep dose response relationships in terms of safety and efficacy establishing an unfavorable therapeutic index, a decision was made to terminate the study.

# Detail Summary Sheet

Date: 22 Aug 90 Proj No: C-92-88 Status: Ongoing  
 Title: Domperidone (R 33,812) Compassionate Clearance Single Patient Protocol

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator Eddie Starnes, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: John G. Carrougner, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 13 Aug 90	Results Continue

Objective(s): To treat patients with gastric stasis who have failed conventional forms of therapy.

Technical Approach: Only patients who have failed all other forms of therapy meeting the eligibility criteria may be entered on this study. Therapy will follow the schema outlined in the study protocol.

Progress: This study concerns two patients with severely symptomatic delayed gastric emptying of solids, one secondary to diabetes mellitus and the other idiopathic. Both had failed all conventional forms of therapy and were entered in a treatment protocol for the experimental medication, domperidone, on a compassionate clearance basis. Both patients had immediate, dramatic and ongoing sustained benefits from the medication and wish to continue. To date, neither patient has had significant side effects from the medication.

# Detail Summary Sheet

Date: 18 Sep 90	Proj No: C-17-89	Status: Ongoing
Title: Modification of Diet in Renal Disease Study		

Start Date 20 Dec 88	Est Comp Date:
Principal Investigator (vice Tapp) Steven F. Gouge, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: Dietary Staff, Univerity of Texas Health Science Center, San Antonio
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 29 Jan 90	Results Continue

Objective(s): To determine if one of two therapies can slow or prevent the development of end stage renal disease in patients with chronic renal disease: 1) a diet restricted in protein and phoshporus and/or 2) one of two levels of blood pressure control (mean arterial pressure less than 107 or less than 92).

Technical Approach: Participants will be assigned to an appropriate diet programs as determined by the dietary staff at the University of Texas Health Science Center and followed on a regular basis.

Progress: Fifteen patients have been secreened, and three patients randomized during this reporting period. This is a four-year study and enrollment is ongoing.

### Detail Summary Sheet

Date: 29 Nov 90	Proj No: C-20-89	Status: Completed
Title: Transplantation of Human Basal Cell Carcinoma to C57/BALB/C gb <sup>J</sup> /bg <sup>J</sup> NU/NU (beige-nude) Mouse.		

Start Date 20 Dec 88	Est Comp Date:
Principal Investigator Larry E. Becker, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate investigators: Ronald E. Grimwood, Col, USAF, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To transplant human basal cell carcinoma to the C57 beige-nude mouse, and to utilize this animal model to study aspects of the biology of BCC.

Technical Approach: Forty male Beige-Nude mice were transplanted with human BCC, (5 of which were cases obtained from Dermatology Service, BAMC) utilizing our reported subcutaneous implantation technique. Initial volume and wet weight were determined for each tumor. The tumors were measured every two weeks by calipers, with a final volume determined at 120 days at which time the tumors were harvested, weighed, and processed for routine histology. Only those tumors demonstrating typical BCC histology were included in the final data.

Progress: This study has been completed. However, no results are available due to transfer of the associate investigator.



# Detail Summary Sheet

Date: 18 Sep 90 Proj No: C-22-89 Status: Completed  
 Title: Selenium Deficiency in Patients on Chronic Dialysis: Laboratory and Clinical Manifestations

Start Date 27 Jan 89	Est Comp Date:
Principal Investigator David Charney, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: Steven Gouge, MAJ, MC Gerald Merrill, GS-11 Ronald Shippee, MAJ, MS
Key Words: Selenium deficiency	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 56	
Total Number of Subjects Enrolled to Date: 100	
Date of Periodic Review 12 Mar 90	Results Continue

Objective(s): To determine if patients on chronic dialysis are selenium deficient by comparing them with normal controls and patients with near-end-stage renal disease.

Technical Approach: We previously reported normal levels of RBC selenium (SE) and glutathione peroxidase (GPx)--a Se-dependent enzyme--in a group of hemodialysis patients (HD). To investigate this further, we measured levels in a second cohort of HD, studied dialyzer Se clearance, and analyzed 3-day diet histories to evaluate dietary Se intake.

Progress: No difference between pre- and post-dialyzer RBC or plasma selenium was seen with pre- and post-dialyzer RBC or plasma Se was seen with either cellulose (n=11) or polysulfone (n=9) membranes. There was no significant difference in dietary Se intake between controls (48.9±7.97 µg/day, n=16) and HD (53.5±6.77 µg/day, n=24).

We conclude that there is no evidence of abnormalities of Se balance in HD. As such, Se deficiency should not be contributing to the uremic syndrome in such patients.

# Detail Summary Sheet

Date: 18 Sep 90      Proj No: C-23-89      Status: Ongoing  
 Title: Retrospective Analysis of Acute Exacerbations of Chronic Renal Failure

Start Date 27 Jan 89	Est Comp Date:
Principal Investigator Steven F. Gouge, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the risk factors for, clinical presentations and outcomes of acute exacerbations of chronic renal failure; and to compare these variables in patients to patients with chronic renal failure without exacerbation and patients with acute renal failure without prior chronic renal failure.

Technical Approach: Records of patients with a discharge diagnosis of acute renal failure, CRF, or both during the period 1986 and 1987 will be reviewed.

Progress: Chart review is virtually complete. Data analysis has just begun and indicates that patients with acute renal failure de novo are similar to those with chronic renal failure.

# Detail Summary Sheet

Date: 12 Sep 90 Proj No: C-24-89 Status: Ongoing  
 Title: Rate Dependent Toxicity of Amphotericin B Infusion

Start Date 27 Jan 89	Est Comp Date:
Principal Investigator David P. Dooley, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, COL, MC Craig E. Smith, MAJ, MC James K. Gilman, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 12 Mar 90	Results

Objective(s): To conduct a trial to compare the relative toxicities of low versus rapid infusion of Amphotericin B (AMB).

Technical Approach: Data will be collected before, during, and after a single day's infusion of AMB. A 500 ml bag of AMB will be hung and allowed to run over either a 1 or 4 hour period. Each patient will be observed for two, and hopefully four, infusion, on two separate days. Each patient will alternately receive both speeds of infusion, with alternate patients receiving a one hour infusion on the first day and a four hour infusion on the second; versus the long, then short infusion on successive days. Subjective and objective data collected at the bedside on each patient will be tabulated.

Progress: Early data show one hour infusion to have no more toxicity than the four hour.

# Detail Summary Sheet

Date: 3 Oct 90 Proj No: C-30-89 Status: Terminated

Title: The Effect of Folinic Acid in the Prevention of Leukopenia in AIDS Patients Treated with Trimethoprim/Sulfamethoxazole of Pneumocystis carinii Pneumonia

Start Date 21 Feb 89	Est Comp Date:
Principal Investigator J. William Kelly, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, COL, MC David P. Dooley, MAJ, MC
Key Words: Pneumonia, <u>Pneumocystis carinii</u>	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the effect of folinic acid in the prevention of leukopenia in AIDS patients treated with high doses trimethoprim/sulfamethoxazole (T/S) for Pneumocystis carinii pneumonia (PCP).

Technical Approach: Patients will be randomly assigned to one of three groups to be treated with T/S for a total of 21 days. Group I will receive folinic acid, 15 mg daily; Group II will receive folinic acid only if the WBC becomes less than 3000 and Group III, the control group, no folinic acid. All patients will have serum folate, red cell folate, serum B12 level, CBC, reticulocyte count, PMN lobe count, BUN, creatinine, SGOT, SGPT, LDH, and total bilirubin obtained prior to therapy. Daily CBC, platelet counts, and PMN lobe counts will be obtained. Daily reticulocyte counts will be obtained in patients in Group II to monitor response. Patients in Groups I and II will have reticulocyte counts should the WBC becomes less than 3000 or platelet count less than 80,000. Trimethoprim and sulfamethoxazole levels will be obtained on day 3 of therapy.

Progress: Study terminated due to marked decrease in PCP cases after PCP prophylaxis became standard of care.

# Detail Summary Sheet

Date: 15 Mar 90 Proj No: C-31-89 Status: Terminated  
 Title: Primary Prophylaxis with Aerosolized Pentamidine in HIV Patients at High Risk for Pneumocystis carinii Pneumonia

Start Date 21 Feb 89	Est Comp Date:
Principal Investigator J. William Kelly, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, COL, MC David P. Dooley, MAJ, MC
Key Words: Pneumonia, <u>Pneumocystis carinii</u>	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 Mar 90	Results Terminate

Objective(s): To compare the efficacy of three dosage regimens of aerosolized pentamidine for primary prophylaxis in HIV patients who have been identified at high risk for the development of Pneumocystis carinii pneumonia.

Technical Approach: Patients will be randomly assigned to one of three groups: Group I will receive inhaled pentamidine 150 mg biweekly, and Group II and II will receive inhaled pentamidine 300 mg and 150 mg monthly, respectively. All patients will have baseline T-cell studies, serum immunoglobulin levels, CBC, SMA-17, urinalysis, anergy panel, ESR, pulmonary function testing, gallium scan and Technetium 99 DTPA scan prior to therapy. Laboratory follow-up will consist of CBC, SMA-17, T-cell studies, and quantitative immunoglobulins, every 3 months, and CXR every six months. Prophylaxis will be discontinued when the patient is diagnosed as having PCP or develops intolerance to the drug.

Progress: This study was terminated due to inability to obtain respiratory therapy support.

# Detail Summary Sheet

Date: 8 Aug 90 Proj No: C-36-89 Status: Ongoing  
 Title: A Prospective, Double Blind Study of Retrovir in Early HIV Infection

Start Date: 23 Feb 89	Est Comp Date:
Principal Investigator J. William Kelly, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, COL, MC
Key Words: HIV infection	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 12 Mar 90 Results Continue follow-up	

Objective(s): To evaluate the safety and tolerance of chronic administration of Retrovir in adult patients with early manifestations of ARC, including those presenting with only HIV-associated lymphadenopathy and a CD4 cell count  $< 500$  cells/mm<sup>3</sup>, and to assess the efficacy of Retrovir therapy in the treatment of HIV disease in these patients.

Technical Approach: This will be a placebo-controlled, double-blind study to evaluate the effect of 800 mg/day of oral Retrovir on the clinical, immunologic and virologic manifestations of early AIDS-Related Complex. Patients entering this trial will have signs and symptoms consistent with early stages of the disease and CD4 cell number  $< 500$  but  $> 200$  cells/mm<sup>3</sup>. The safety and tolerance of retrovir in this population will also be evaluated. Patients will be randomized to receive either Retrovir or placebo capsules for 96 weeks. Study medicines will be administered at a dose of 200 mg every 6 hours.

Progress: All patients enrolled on this study have been switched to open label AZT. The patients will continue to be followed.

# Detail Summary Sheet

Date: 26 Sep 90	Proj No: C-38-89	Status: Ongoing
Title: The Effects of Beta Blockade on Rest and Exercise Hemodynamics in Patients with Mitral Stenosis		

Start Date: 28 Feb 89	Est Comp Date:
Principal Investigator Thomas L. Ashcom, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Steven R. Bailey, MAJ, MC Joseph P. Johns, MAJ, MC
Key Words: Beta blockade Mitral stenosis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$11,050.00
Number of Subjects Enrolled During Reporting Period: 10	
Total Number of Subjects Enrolled to Date: 10	
Date of Periodic Review 6 Mar 90	Results Continue

Objective(s): 1) Obtain simultaneous left and right heart high fidelity hemodynamic pressures in patients with mitral stenosis under conditions of rest, exercise and beta blockade.

2) Study the interrelationships between valve area, cardiac output, diastolic filling period, and mitral valve gradient, systolic, diastolic function in patients with mitral stenosis under the above conditions.

3) Correlate data obtained by cardiac catheterization to non-invasive evaluation of echo-Doppler under similar conditions of rest, exercise and beta-blockade.

Technical Approach: To study the effects of beta blockade (BB) on transmitral gradient, cardiac output, and exercise capacity, 10 patients with mitral stenosis (MS) were exercised in a double blind, randomized, placebo-controlled, crossover protocol. Each patient took either 100 mg of atenolol or placebo for one week and then underwent upright bicycle ergometry until exhaustion. Mitral and aortic flow velocities were assessed at maximum exertion by continuous wave Doppler. Computer digitization of mitral and aortic flow signals was performed to evaluate peak velocity, mean gradients, and cardiac output. A metabolic cart was used to provide objective data on maximal O<sub>2</sub> consumption, anaerobic threshold, and exercise time. Exercise was repeated one week later with the alternate drug.

Progress: BB reduced heart rate and mean transmitral gradient with exercise; however, cardiac output and exercise performance were significantly impaired with no subjective improvement.

C-38-89 (continued)

One of the drawbacks of the present study is that it was not designed to assess the effects of beta blockade on patient's symptoms or the physiological significance of the impaired cardiac output secondary to BB. Use of BB in patients with mitral stenosis demonstrates a beneficial hemodynamic response. Whether symptoms of low output or fatigue may replace those of pulmonary congestion remains to be seen with prospective studies designed to evaluate the outcome of chronic beta blockade therapy in mitral stenosis.



# Detail Summary Sheet

Date: 25 Sep 90 Proj No: C-39-89 Status: Terminated  
 Title: Assessment of Revascularization via Coronary Artery Bypass Grafting by  
 Dipyridamole-Thallium Scintigraphy

Start Date 28 Feb 89	Est Comp Date:
Principal Investigator James K. Gilman, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Ricky D. Latham, MAJ, MC Vincent Pearson, LTC, MC Brent Grishkin, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review _____	Results _____

Objective(s): To determine the utility of dipyridamole-Thallium scintigraphy as a noninvasive modality to assess the completeness of revascularization at coronary bypass surgery.

Technical Approach: Pre- and postoperative dipyridamole-Thallium scintigraphic studies will be performed on forty patients undergoing elective coronary artery bypass surgery. The ability of this imaging modality to demonstrate incompletely revascularized hearts will be assessed by comparing the results of dipyridamole-Thallium scintigraphy with the results of post-CABG cardiac catheterization. Patients will be followed prospectively to determine whether patients with redistribution abnormalities on dipyridamole-Thallium scintigraphy are more likely to re-present with angina or infarction in the first postoperative year.

Progress: No progress has been made since last report. Protocol discussed at several staff meetings without generation of any new interest or patient referrals. Therefore the study is terminated.

# Detail Summary Sheet

Date: 25 Oct 90 Proj No: C-40-89 Status: Completed  
 Title: Beat-to-Beat Analysis of Pulmonary Compliance in Normal Man at Rest and with Exercise

Start Date 28 Feb 89	Est Comp Date:
Principal Investigator David M. Slife, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Ricky D. Latham, MAJ, MC
Key Words: Pulmonary compliance	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$6,750.00 AFSGO Funded
Number of Subjects Enrolled During Reporting Period: 8	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review	Results

Objective(s): 1) Analyze resting steady state compliance as determined by the three-element Windkessel model in 10 patients.

2) Compare the model-derived pulmonary characteristic impedance and pulmonary resistance with that obtained by the conventional manner at rest.

3) Compare model-derived compliance at rest to values obtained during steady state supine exercise.

4) Compare the three-element Windkessel model to a distributed model for pulmonary compliance and estimate the percentage to total compliance contributed by the pulmonary vasculature.

Technical Approach: Eight normal patients were studied using multisensor micro-manometry technology and had simultaneous rest and exercise pulmonary artery pressures (PAP) and flows (PAF) recorded. These were submitted to the parameter estimation procedure which determined Cp, Zc, and PVR. These parameters were also independently derived with the Zc and PVR being calculated using Fourier analysis of the PAP and PAF, and CP being estimated by the ratio of stroke volume to pulse pressure.

Progress: Significant changes in the heart rate, pulmonary pressures and stroke volume ( $p < 0.05$ ) occurred with exercise. Zc and PVR values returned by the model were compared to those independently calculated variables at rest and during exercise and showed no significant difference. There was also no significant difference between the rest and exercise values of ZC or PVR by either method. Comparison of model-derived estimates of CP to independently calculated values

C-40-89 (continued)

were significantly different at rest ( $p < 0.04$ ) as well as exercise ( $p < 0.001$ ). However, there was no significant difference between rest and exercise values of  $C_p$  by either method. The modeled estimates of PVR at rest  $64 \pm 11 \text{ d} \cdot \text{s} \cdot \text{cm}^{-5}$  and exercise  $22 \pm 3 \text{ d} \cdot \text{s} \cdot \text{cm}^{-5}$  were appropriate. The modeled  $C_p$  values at rest ( $0.22 \pm .05 \text{ ml/mmHg/kg}$ ) correlated with previously reported normalized values in other species. Therefore, the three-element Windkessel model appears to estimate the arterial compliance in the pulmonary circulation accurately. This technique offers the advantage of evaluating pulmonary arterial compliance in vivo in man. The changes in the parameters with exercise are possibly due to independent alterations of  $C_p$  and the total resistive load between the central and peripheral pulmonary circulation. This study reports the first use of a parameter estimation procedure based on the three-element Windkessel model to describe pulmonary artery parameters -  $C_p$ ,  $Z_c$ , and PVR - and the first evaluation of these parameters at rest and with exercise in man.

# Detail Summary Sheet

Date: 27 Sep 90 Proj No: C-46-89 Status: Terminated  
 Title: Effect of Topical Minoxidil on Nail Growth

Start Date 28 Feb 89	Est Comp Date:
Principal Investigator Larry E. Becker, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators: Joseph P. Johns, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To evaluate the effectiveness of a 5% topical solution of minoxidil versus placebo to stimulate (increase rate) of nail growth in normal volunteers.

Technical Approach: As outlined in the company protocol.

Progress: No patients have been enrolled on this study. After screening several patients for possible inclusion, it became obvious that without a volunteer fee it would be impossible to recruit any subjects. Funding for the protocol was never approved by the USUHS Jackson Foundation. Review by the USUHS required several protocol revisions. This was not possible with this being a multicenter study (the other centers were non-military universities).

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-49-89 Status: Completed  
 Title: Percutaneous Endoscopic Gastrostomy: A Three Year Experience at Brooke Army Medical Center

Start Date 20 Mar 89	Est Comp Date:
Principal Investigator Harold Sullivan, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To review the BAMC experience with this relatively new endoscopic technique for placing a gastrostomy tube by a nonsurgical approach.

Technical Approach: All records of patients having undergone gastrostomy or percutaneous endoscopic gastrostomy (PEG) since July 1986 will be reviewed. All pertinent information will be recorded. The broad categories of specific information will include indication, technique, pre-procedure blood test results, immediate and late complications, mortality, and follow-up.

Progress: All available records reviewed. 79 PEGs were performed. 46 were for CNS disorders, 20 were for cancer, and 13 miscellaneous. Morbidity was 20% including aspiration; however, aspiration due to CNS disorder and swallowing difficulty were present in 97% of patients prior to PEG. Therefore, overall complications were 11%.

# Detail Summary Sheet

Date: 18 Sep 90                      Proj No: C-55-89                      Status: Ongoing  
 Title: Arterial Healing After Percutaneous Sheath Cannulation: Prospective Study to Determine the Natural History of Pseudoaneurysm Formation

Start Date: 3 Apr 89	Est Comp Date:
Principal Investigator	Facility
Joseph P. Johns, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Cardiology	Lawrence E. Pupa, MAJ, MC
Key Words:	Steven R. Bailey, M.D.
	Roger J. Belbel, CPT, MC
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 14 May 90	Results Continue

Objective(s): It is hypothesized that pseudoaneurysms may transiently develop after percutaneous arterial cannulation and may be present during the early phase of arterial healing. This study will explore this hypothesis through prospective serial echocardiographic evaluation of arteries after percutaneous vessel cannulation.

Technical Approach: The natural history of arterial healing after percutaneous vessel cannulation is poorly understood; however, complications at the arterial site rarely occur and can lead to patient morbidity. This study is designed to prospectively examine the natural history of arterial healing in a large group of patients after arterial cannulation to determine the true frequency of pseudoaneurysm formation, and to examine the hypothesis that pseudoaneurysms may spontaneously resolve in some patients. Approximately 500 patients will be studied through noninvasive ultrasound techniques which place the patient at no additional risk, and which permit serial evaluation of changes at the arterial site. This information may lead to better management of patients who develop these arterial complications.

Progress: No patients have been enrolled on this study due to failure to receive vascular transducer.

# Detail Summary Sheet

Date: 20 Sep 90 Proj No: C-56-89 Status: Terminated

Title: Serum Levels of T4, T3, free T4, free T3, and TSH with Progressive Increments of Thyroid Hormone Replacement in Patients with no Intrinsic Capability of Producing Thyroid

Start Date: 3 Apr 89	Est Comp Date:
Principal Investigator Albert M. Thomason, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Endocrinology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
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Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review \_\_\_\_\_ Results \_\_\_\_\_

Objective(s): To demonstrate the effect of incremental increases of thyroid hormone on the serum thyroid hormone levels in the individual patient from the hypothyroid to the hyperthyroid state.

Technical Approach: Fifteen volunteers would be solicited among those with a history of thyroid ablation for thyroid cancer who are undergoing a total body scan after being off thyroid hormone therapy for 6 weeks. After the scan is completed the patient would be asked to return for daily blood sampling and started on a thyroid replacement dosage of 0.025 mg daily. The patient would remain on this dose until the serum T4 value shows no change over a period of 3 days. At this time the free hormone levels and the reverse T3 levels would be measured in addition to the routine thyroid studies. Then the patient would have an increment in hormone dosage of 0.025 mg and have daily measurements of thyroid functions until a new steady state of T4 level is revealed. The increments in l-thyroxine dosage would be continued until the patient reaches a serum triiodothyronine level of greater than 200 mg/dl. Thyroid dosage would subsequently be adjusted to keep the patient mildly thyrotoxic and to keep the TSH value unmeasurable, the usual level for a thyroid cancer patient.

Progress: Of the few patients having total body scans this last year, none was suitable to approach as a volunteer, mainly because of not being a local resident or not being able to take time off to come in. Therefore, the study was terminated.

# Detail Summary Sheet

Date: 22 Aug 90	Proj No: C-57-89	Status: Ongoing
Title: The Endogenous Opioid System in Tourette Syndrome		

Start Date: 4 Apr 89	Est Comp Date:
Principal Investigator (vice Atkinson) Wayne Gordon, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Neurology	Associate Investigators:
Key Words: Tourette Syndrome	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 11 May 90	Results Continue

Objective(s): To evaluate the effectiveness of Naltrexone in controlling the disabling movements of Gilles de la Tourette Syndrome (TS), and to assess neurotransmitter function in TS both while on Naltrexone and off medication.

To determine if abnormalities exist of function or regional blood flow in brains of patients with Gilles de la Tourette syndrome (TS).

Technical Approach: Ten patients over age 6 referred to the Pediatric Neurology Service whose clinical symptoms give them a diagnosis of TS will be studied. Each patient will serve as his own control in a double blinded cross-over control fashion with groups beginning as on medication (a) or on placebo (B). There will be a one week washout between phases. Dosages of Naltrexone will be adjusted according to weight and size and will vary from 25 mg BID to 75 mg BID. Measurement of the efficacy of Naltrexone will be done by a questionnaire to each patient. Spinal puncture will be done on all patients as part of the evaluation of the movement disorder.

Progress: Three patients have been entered into the study. Since the principal investigator has transferred to William Beaumont Army Medical Center, it is planned to continue the study in collaboration with him in an effort to obtain an adequate number of study subjects.



# Detail Summary Sheet

Date: 18 Sep 90 Proj No: C-60-89 Status: Ongoing  
 Title: A Pilot Trial of Late Thrombolysis and Delayed Revascularization in  
 (Late) Myocardial Infarction

Start Date: 4 Apr 89	Est Comp Date:
Principal Investigator (vice Condos) Lawrence E. Pupa, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: J. Mark Moody, LTC, MC W. Randy Condos, LTC, MC John-Francis M. Hennecken, MAJ, MC James K. Gilman, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 198 (nationwide)	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): 1) To compare the patency rate of Activase® versus placebo with acute myocardial infarction presenting 6-24 hours after the onset of symptoms.

2) To assess the efficacy (ventricular function) of acute PTCA in patients with occluded infarct arteries 6-24 hours after the onset of symptoms.

3) To determine the relationship between infarct artery patency, ventricular function, and clinical outcomes.

Technical Approach: This is a parallel group, randomized double blind placebo-controlled trial comparing Activase® with placebo. One hundred patients will be randomized to each drug treatment group. The coronary angiogram upon which the efficacy determination will be based will be the first injection of the IRA performed between 6 and 24 hours following the start of infusion. At this time left ventriculography will be performed to measure left ventricular function. If the infarct related artery is patent, the patient will be returned to the CCU for monitoring. If the vessel remains occluded the eligible patient will be randomized to either PTCA or no PTCA. A rest and exercise gated blood pool scan will be performed 4-6 weeks post-treatment. A second coronary angiogram and ventriculogram will be performed 4-6 months post-treatment.

Progress: This is a multicenter study. Data are being analyzed at National coordinating centers. Final report will be submitted upon receipt.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-61-89 Status: Completed  
 Title: Comparative Efficacy and Safety of Fleet Hypertonic Phosphate Enema, Water Enema, and Colyte Enemas for Flexible Sigmoidoscopy - A Double Blind Randomized Study

Start Date: 26 Apr 89	Est Comp Date:
Principal Investigator Shailesh C. Kadakia, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Charles Cohan, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 60	
Total Number of Subjects Enrolled to Date: 63	
Date of Periodic Review 14 May 90	Results Continue

Objective(s): To compare the efficacy and safety of Fleet Hypertonic Phosphate Enema (HPE), water enema, and Colyte enemas used as cleansing solutions for flexible sigmoidoscopy in patients who are having flexible sigmoidoscopy for screening and diagnostic evaluation.

Technical Approach: Over a one year period 60 patients scheduled for flexible sigmoidoscopy were randomized to receive two bottles of enema solution, both of which contained either Fleet (20), water (18), or Golytely (22). Venous blood samples were collected immediately pre- and post enema administration and analyzed for BUN, Creat, Na, K, Cl, CO<sub>2</sub>, Ca, PO<sub>4</sub>, and pH. Enema retention time was 5 minutes per enema. Flexible sigmoidoscopy was performed and the efficacy of the enemas graded in four categories - excellent (0% obscuration), adequate (<10%), mediocre (<25%), and poor (>25%).

Progress: Na, K, Cl, CO<sub>2</sub>, Ca, and pH values were not significantly different between the three enema groups. The fleet enema group significantly increased levels of PO<sub>4</sub> after the enema (p < .001) when compared to the water or Golytely enema groups. This increase ranged from 0.0 mg to 0.8 mg/dl, but remained within the normal limits. The Fleet enema was demonstrated to be significantly more efficacious (p < .001) than the water or Golytely enema in preparing the rectum and sigmoid colon for flexible sigmoidoscopy.

C-61-89 (continued)

Conclusion: When the duration of enema retention is controlled, the use of the Fleet enema results in a slight, clinically benign, and significantly increased level of serum  $\text{PO}_4$  when compared to water and Golytely enemas. Use of the Fleet enema results in a more efficacious cleansing of the rectum and sigmoid colon when compared to water or Golytely preparations.

# Detail Summary Sheet

Date: 22 Aug 90 Proj No: C-63-89 Status: Ongoing  
 Title: What is the Value of Fecal Occult Blood Tests Performed at the Time of Digital Rectal Examination?

Start Date: 26 Apr 89	Est Comp Date:
Principal Investigator (vice Cohan) Shailesh Kadakia, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators:
Key Words:	Eddie Starnes, COL, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 16	
Total Number of Subjects Enrolled to Date: 16	
Date of Periodic Review 11 May 90	Results Continue

Objective(s): To determine the clinical meaning and usefulness of positive fecal occult blood tests (Hemoccult Method) discovered at the time of routine digital rectal examination.

Technical Approach: Adult patients over the age of 40 with positive hemoccult tests obtained on normal-appearing stool obtained at rectal examination will be eligible. All patients will be offered the standard of care which includes full evaluation of the lower GI tract (colonoscopy or flexible sigmoidoscopy/air contrast barium enema) and possibly the upper GI tract. Stool Hemoccult II samples will be collected on three consecutive days in the usual maner. Hemoquant assays will be obtained on the same spontaneously passed stool specimens used for Hemoccult II testing.

Progress: Sixteen patients have been enrolled thus far. Number of patients is too small to draw any conclusions or report any significant results.

# Detail Summary Sheet

Date: 18 Sep 90 Proj No: C-64-89 Status: Ongoing  
 Title: Hemodynamic Response to Maximal Supine Exercise

Start Date: 5 May 89	Est Comp Date:
Principal Investigator Timothy J. Martin, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: David M. Slife, MAJ, MC James Johnson, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 7	
Total Number of Subjects Enrolled to Date: 7	
Date of Periodic Review 14 May 90 Results Continue	

Objective(s): To characterize the hemodynamic response to maximal supine exercise in normal human volunteers.

Technical Approach: Fifteen male or female subjects referred for cardiac catheterization and between the ages of 18 and 75 will be eligible to participate. Each subject will perform progressive supine cycle exercise while intracardiac pressures, cardiac output, and oxygen consumption are measured.

Progress: Seven patients have been enrolled - six normals and one with increased blood pressure. The latter patient suffered brachial arterial thrombosis requiring surgical repair; this is an accepted complication of catheterization. Progressive exercise has had variable response on intracardiac pressures, e.g. some increase some decrease. "n" too low to make broad statements.

# Detail Summary Sheet

Date: 22 Aug 90	Proj No: C-70-89	Status: Ongoing
Title: Rifampin for Infusion (Compassionate Use Protocol)		

Start Date: 15 May 89	Est Comp Date:
Principal Investigator J. William Kelly, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 11 May 90	Results Continue

Objective(s): To provide intravenous rifampin for "humanitarian" use on specific cases.

Technical Approach: Any patient satisfying one or more of the following criteria will be considered eligible for treatment with rifampin IV: 1) active tuberculosis where the drug cannot be taken by mouth, patients who do not tolerate oral medication, and in comatose patients (tuberculous meningitis); 2) infections with microorganisms resistant to approved antibiotics; (3) in patients with in vitro sensitivity tests positive to an approved antibiotic but who develop an allergy or exhibit an adverse reaction to that antibiotic, or whose disease is serious enough to warrant treatment with an investigational drug. Lyophilized rifampin will be reconstituted and administered according to established procedures.

Progress: One patient was enrolled and tolerated the medication without difficulty. The study remains open for compassionate use only.

# Detail Summary Sheet

Date: 18 Sep 90	Proj No: C-73-89	Status: Ongoing
Title: Phase I Study of SK&F 104864-A Administered as a Single Intravenous Dose Every 21 Days		

Start Date: 7 Jun 89	Est Comp Date:
Principal Investigator James G. Wall, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Hem. Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 11	
Total Number of Subjects Enrolled to Date: 18	
Date of Periodic Review 14 May 90	Results Continue

Objective(s): 1) To determine the maximal tolerated dose of SK&F 104864-A given as a single dose every 21 days.

2) To determine the qualitative and quantitative toxicities of SK&F 104861-A.

3) To determine the recommended dose for SK&F 104864-A as a single dose every 21 days to be used in Phase II trials.

Technical Approach: Eligible patients will receive therapy as outlined in the study protocol.

Progress: We continue to accrue patients in conjunction with the University of Texas Health Science Center at San Antonio. Myelosuppression, alopecia, fever, chills, and mild nausea and vomiting have been observed. We believe we are nearing the maximal tolerated dose, with myelosuppression being the likely dose-limiting toxicity.

# Detail Summary Sheet

Date: 26 Sep 90 Proj No: C-74-89 Status: Ongoing  
 Title: A Phase I/II Clinical Trial to Evaluate the Safety and Efficacy of a Weekly Administration of Brequinar Sodium (DuP 785) in Combination with an Every Three Week Administration of Cisplatin in Cancer Patients with...Solid Tumors

Start Date: 7 Jun 89	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Hem. Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 12 (18)*	
Total Number of Subjects Enrolled to Date: 17 (23)*	
Date of Periodic Review 14 May 90	Results Continue

Objective(s): 1) To identify the maximum tolerable dose, dose-limiting toxicities and recommended dose(s) for efficacy trials of DuP 786 when administered on a once-a-week basis in combination with an every-three-week schedule of cisplatin in patients with cancer refractory to conventional therapy or in patients for whom no standard therapy exists.

2) To characterize the safety and toxicity profiles of DuP 786 plus cisplatin combination chemotherapy regimen.

3) To evaluate the clinical efficacy of the combination regimen consisting of the recommended dose of DuP 785 plus standard dose cisplatin.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: The Phase I portion of this joint (BAMC/UTHSC) study is near completion. A total of 23 patients have been enrolled on study (18 at BAMC and 5 at UTHSC). The predominant toxicity is myelosuppression which is dose limiting. The recommended dose for the Phase II portion of this trial will be cisplatin 75mg/m<sup>2</sup> and Brequinar 860mg/m<sup>2</sup>.



# Detail Summary Sheet

Date: 18 Sep 90 Proj No: C-75-89 Status: Ongoing  
 Title: An Investigation of Locus of Control in Dialysis Patients  
 (Collaborative Study with University of Texas Health Science Center)

Start Date: 9 Jun 89	Est Comp Date:
Principal Investigator Steven R. Gouge, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 14 May 90 Results Continue	

Objective(s): To investigate the locus of control of patients in renal failure.

Technical Approach: A locus of control instrument and a questionnaire will be administered to 200-300 patients presently undergoing dialysis.

Progress: Patient accrual has been completed. Data analysis is underway.

# Detail Summary Sheet

Date: 18 Sep 90 Proj No: C-82-89 Status: Completed  
 Title: Serum Angiotensin Converting Enzyme Elevation in Patients with HIV-I Infection. A Controlled, Prospective Study

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Daniel R. Ouellette, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary	Associate Investigators: Gregg T. Anders, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): To evaluate the use of the serum ACE level as a convenient marker and correlate for macrophage function in the progression of HIV infection.

Technical Approach: A total of 50-60 subjects will be evaluated. Study groups will be arranged into four major divisions: 1) normal controls, consisting of 12-15 active duty HIV-seronegative volunteers, 2) asymptomatic HIV-seropositive patients, 12-15 total; 3) AIDS-related complex, or ARC patients, 12-15 total; and 4) 12-15 patients with AIDS. Serum angiotensin-converting enzyme (ACE) levels will be obtained via venipuncture during the routine evaluation of study groups 2, 3, and 4. Normal volunteers will have venipuncture performed either by the PI or the staff monitor. The mean values for serum ACE will be compared among groups, and CD4 levels will be compared and correlated with ACE levels as well.

Progress: ACE levels have been obtained in 62 patients with various stages of HIV disease and in 16 cntrol subjects. Patients have been categorized by Walter Reed staging criteria. The average ACE level for controls is  $31.88 \pm 13.95$ . This is significantly different than all HIV patients where the average is  $52.94 \pm 23.19$ . Twenty-two patients with Walter Reed Stage I disease - average ACE is  $45.59 \pm 20.40$  which is significantly different than controls ( $p = 0.026$ ). Walter Reed Stages 2 and 3 account for 25 patients with an average ACE level of  $53.56 \pm 24.56$  which is significantly different than controls ( $p = 0.0027$ ). Walter Reed Stages 4 and 5 account for 10 patients with an average ACE level of  $66.3 \pm 25.92$  which is significantly different than control ( $p = 0.00012$ ). Walter Reed Stage 6 accounts for 5 patients with average ACE level of  $55.4 \pm 11.44$  which is significantly increased compared to controls ( $p = 0.0029$ ).

C-82-89 (continued)

Conclusions: ACE levels are elevated early during HIV infection. ACE levels tend to increase with disease progression. Serum ACE levels may be a good marker for HIV disease.

# Detail Summary Sheet

Date: 16 Oct 90 Proj No: C-85-89 Status: Ongoing  
 Title: Introduction of TNF-alpha in Human Infection by Coccidioides immitis  
 (Collaborative Study with Wilford Hall USAF Medical Center)

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator (vice Kelly) David P. Dooley, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: Matthew J. Dolan, CPT, USAF MC Rebecca A. Cox, Ph.D. J. William Kelly, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$12,690.00 AFSGO-\$2500.00 DCI
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine whether human infection with Coccidioides immitis results in the production of tumor necrosis factor (TNF-a)/cachetin.

Technical Approach: Subjects were stratified according to stage of coccidioidomycosis infection: skin test negative (never infected, n=6), skin test positive only (infected, no disease; n=4), and treated, resolved active pulmonary disease (n=1). Peripheral blood mononuclear cells (PBMCs) were isolated, fractionated, and the adherent cell population (>90% monocytes) were incubated overnight with either killed spherules of Coccidioides immitis or the nonspecific stimulant lipopolysaccharide (LPS).

Progress: Monocytes from all subjects secreted low but detectable levels of TNF-a in response to spherules. No significant differences between groups in the amount of TNF-a secreted was detectable when monocytes were exposed to a wide range of spherule concentrations. As expected, the three study groups produced comparable levels of TNF-a in response to LPS.

Low level induction of TNF-a may be associated with increased TNF-a mRNA transcription and subsequent biologically active membrane association with the molecule, in the absence of measurably secreted amounts (within the limits of assays for secreted cytokines). To investigate this, we will utilize a polymerase chain reaction (PCR) which has the capability of detecting picogram amounts of TNF-a specific mRNA (or, conversely, mRNA obtained from as few as 20 PBMCs). Experiments will be performed comparing differences in the induction of TNF-a mRNA between study groups following exposure to spherules at lower, more physiologic concentrations (doses previously associated with no or minimal amounts of secreted TNF-a). Similar experiments are planned to measure TNF-a

mRNA induction (by PCR) from the cloned human monocytic THP-1 cell line, which in preliminary experiments was shown to secrete TNF- $\alpha$  at low levels in response to both LPS and spherules.

It is possible that induction of cytokines such as TNF- $\alpha$  or interferon- $\gamma$  (IFN- $\gamma$ ; similar to TNF- $\alpha$ , a critical immunomodulatory cytokine implicated in coccidioidomycotic disease, but secreted from T lymphocytes) from spherule-exposed disease PBMCs may require the presence of helper T cells, and that differences between groups may exist when these specific memory cells (presumably present in skin test positive patients only) are included in the system. Thus experiments were performed exposing unfractionated (monocytes and lymphocytes) normal donor PBMCs to spherules, with subsequent assay for secreted IFN- $\gamma$ . While the nonspecific stimulant concanavalin A induced IFN- $\gamma$  secretion, this cytokine was not found to be secreted in response to spherule exposure. Additional experiments using PCR to probe for specific IFN- $\gamma$  mRNA (as described above) transcribed following PBMC exposure to spherules are planned.

As recent data indicate that other cytokines (interleukins [IL] -1, -4, and -6, and granulocyte-macrophage colony stimulating factor [GM-CSF]) demonstrate potent immunomodulatory properties, they may also be critical to the host response to infection with coccidioidomycosis. Therefore, similar experiments will be performed to measure the induction of these cytokines by spherules.

Parallel studies in this laboratory have demonstrated that macrophages isolated from murine peritoneum demonstrated enhanced killing of engulfed, variable spherules following the addition of IFN- $\gamma$  to the system, in a dose-dependent fashion. Similar studies are planned within this protocol, to determine if PBMCs isolated from human subjects can be activated by TNF- $\alpha$  or IFN- $\gamma$  to inhibit growth of C. immitis. The ramifications inherent in this line of investigation for the development of future immunomodulatory therapy for this disease are obvious.

# Detail Summary Sheet

Date: 19 Jul 90 Proj No: C-92-89 Status: Terminated  
 Title: High-Dose Chemotherapy and Autologous Bone Marrow Rescue for Locally Advanced Breast Cancer

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Patrick W. Cobb, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Hem-Oncology	Associate Investigators: Richard O. Guidice, MAJ, MC Barbara Reeb, MT Roy Duncan, SGT Robert G. Whiddon, Jr., LTC, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review _____ Results _____	

Objective(s): To determine the effects of high dose chemotherapy and autologous bone marrow rescue on women with advanced breast cancer.

Technical Approach: All patients meeting the eligibility criteria will receive the standard dose of Cytosan, Adriamycin, and 5-FU (FAC) with cycles repeated every 21 days as blood counts allow to complete four cycles. Choice of local control measures will be at the discretion of the patient and the physicians, and will be done six weeks after the last cycle of FAC chemotherapy. Bone marrow aspiration, cryopreservation, and storage will be done six weeks after the last course of FAC chemotherapy, or after the patient has sufficiently recovered from the local control procedure.

Progress: This study was terminated due to lack of patient accrual.

# Detail Summary Sheet

Date: 10 Sep 90 Proj No: C-98-89 Status: Ongoing  
 Title: Therapy of Dialysis Hypotension with Hypertonic Saline and Dextran

Start Date: 1 Aug 89	Est Comp Date:
Principal Investigator Stephen F. Gouge, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 22	
Total Number of Subjects Enrolled to Date: 22	
Date of Periodic Review 10 Sep 90	Results Continue

Objective(s): To assess the efficacy and side effects of infusing small volumes of hypertonic saline with and without Dextran in the treatment of hemodialysis-induced hypotension.

Technical Approach: This is a randomized, blinded, cross-over study of 40 patients with end-stage renal disease who undergo dialysis two or three times weekly. Three solutions will be tested: (1) 10 cc of 23% NaCl, (2) 30 cc of 7.5% NaCl, and 30 cc of 7.5% NaCl with 6% Dextran 70. When hypotension occurs during dialysis, the assigned solution shall be infused, and the BP and pulse response shall be monitored. Each patient will cross over to receive each of the three solutions during subsequent dialysis sessions in which hypotension occurs.

Progress: Four patients have been studied at BAMC and five at Letterman Army Medical Center. There seems to be a trend toward better results with solutions 1 and 3.

# Detail Summary Sheet

Date: 9 Sep 90	Proj No: C-103-89	Status: Ongoing
Title: Single Patient Protocol for Treatment of Systemic Mycoses with Itraconazole (R51,211)		

Start Date: 2 Aug 89	Est Comp Date:
Principal Investigator Craig E. Smith, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, COL, MC J. William Kelly, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 8 Sep 90 Results Continue	

Objective(s): Compassionate use of drug Itraconazole for treatment of systemic mycoses.

Technical Approach: Eligible patients must have positive culture and/or histologic findings which identify the pathogen. Dosage will be initiated on 100 mg q.d. with a meal and maintained on that dose for at least a month. If patient is unchanged or worsening, dose may be increased in 100 mg increments to a maximum of 400 mg/day. The optimal duration of treatment is unknown, but a treatment course of about one year is planned.

Progress: This study remains open for eligible patients to be enrolled on a compassionate basis. One patient on the study has done well.



# Detail Summary Sheet

Date: 10 Sep 90 Proj No: C-104-89 Status: Ongoing  
 Title: Pilot Study to Screen Serotypes of Klebsiella species and P. aeruginosa

Start Date: 14 Aug 89	Est Comp Date:
Principal Investigator	Facility
J. William Kelly, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Infectious Dis.	
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 10 Sep 90	Results Continue

Objective(s): To determine the serotypes of Klebsiella species and P. aeruginosa that may be encountered in Study CSP 316 and to compare these serotypes to the serotypes included in both vaccines.

Technical Approach: All patients in the intensive care units will be followed for the development of infections with Klebsiella (K) and P. aeruginosa (PA). K and PA isolate will be saved and sent for serotyping. The laboratory of Dr. Alan Cross, Department of Bacterial Diseases, Walter Reed Army Institute of Research, will be designated as the Study Center. The Study Center will coordinate the receipt of cultures and will send the cultures as a large group to Dr. T. L. Pitt, at the Colindale Laboratory, London, England for serotyping.

Progress: Protocol was recently approved. The recent hiring freeze has prevented recruitment of a research nurse.

# Detail Summary Sheet

Date: 17 Jul 90      Proj No: C-105-89      Status: Completed  
 Title: Esophageal Dilation with Savary-Gilliard Bougies Using a Guide Wire with Markings without the Aid of Fluoroscopy

Start Date: 14 Aug 89	Est Comp Date:
Principal Investigator Shaielsh C. Kadakia, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Charles Cohan, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 35	
Total Number of Subjects Enrolled to Date: 53	
Date of Periodic Review	Results

Objective(s): To report our experience in the use of Savary-Gilliard dilators in patients who have undergone esophageal dilation over past three years.

Technical Approach: Fifty three patients with esophageal stricture underwent Savary-Gilliard dilations performed over a marked guide wire which was placed endoscopically. Fluoroscopy was not utilized during the dilations. The dilations were performed only after the guide wire was properly placed with 60 cm markings at the incisors which ensured the tip of the guide wire into the antrum.

Progress: Forty four patients had benign strictures and 9 patients had malignant strictures. There were 90 sessions of dilations for a total of 343 individual individual dilations. In 43 of 53 patients, the guide wire was placed under direct vision in the antrum. The remaining 10 patients had significant esophageal stenosis that prevented the passage of the endoscope into the stomach and therefore the guide wire was placed by advancing it blindly through the stenosis. There were no complications.

Conclusion: The treatment of esophageal strictures using the Savary-Gilliard dilator system and the marked guide wire can be performed safely without the aid of fluoroscopy.

# Detail Summary Sheet

Date: 14 Aug 90 Proj No: C-106-89 Status: Completed  
 Title: What is the Operative Risk in Patients with Severe Pulmonary Disease?

Start Date: 14 Aug 89	Est Comp Date:
Principal Investigator John F. Theroux, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary	Associate Investigators: Greg Anders, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 26	
Total Number of Subjects Enrolled to Date: 26	
Date of Periodic Review	Results

Objective(s): To determine the relationship between severity of pulmonary dysfunction (as measured by spirometry) and operative morbidity/mortality.

Technical Approach: Twenty six patients with severe COPD who underwent thoracic and major abdominal operations were matched with 52 patients with mild COPD and 52 without COPD.

Progress: The 26 COD patients had rates of atelectasis, nonfatal ventilatory failure, and cardiac complications similar to mild COPD and non-COPD patients. They had more bronchospasm (35% vs 15% vs 4%), pneumonia (12% vs 4% vs 2%), supraventricular tachyarrhythmias (35% vs 6% bs 15%), and deaths ((19% vs 4% vs 2%). Mortality clustered primarily in those undergoing coronary artery bypass graft operations. Severe COPD did not result in increased utilization of resources as measured by mechanical ventilator, intensive care, or hospital days. By multivariate analysis, spirometry was a poor predictor of adverse outcomes.

Conclusions: Noncardiac surgery can be safely performed in patients with severe COPD. Coronary artery surgery, however, may pose a greater risk.

# Detail Summary Sheet

Date: 22 Aug 90	Proj No: C-107-89	Status: Ongoing
Title: Phase I Trial of Intrapleurally Administered Alpha Interferon in Malignant Pleural Effusions		

Start Date: 14 Aug 89	Est Comp Date:
Principal Investigator Howard A. Burris, III, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Hem-Oncology	Associate Investigators: Timothy J. O'Rourke, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 Sep 90 Results Continue	

Objective(s): 1) To determine the tolerance to and toxicity of intrapleural administration of Intron-A® in patients with malignant pleural effusions.

2) To determine antitumor activity of Intron-A intrapleurally as evidenced by control of pleural effusions.

Technical Approach: Treatment of eligible patients will follow the schema outlined in the study protocol.

Progress: This study was put on hold prior to any patient enrollment due to there not being an IND for alpha interferon filled with the FDA for this indication. An IND is currently being applied for with the assistance of data from Schering Corporation.

# Detail Summary Sheet

Date: 6 Aug 90	Proj No: C-118-89	Status: Completed
Title: American Andes Biomedical Research Expedition 1989		

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator Winston J. Worme, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine	Associate Investigators: Jeanne DeBolt Worme
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To assess the use of a battery of psychometric and performance tests at altitude and to investigate the use of a high carbohydrate diet at altitude.

Technical Approach: The expedition team consisted of 18 members, 12 of whom were conducting some aspect of the research. Various tests were performed to follow physiologic and cognitive changes and adaptations that occur with such an ascent. All members of the team agree to volunteer for the nutritional portion of the study. The 18 subjects were given access to a standard diet during a five day ascent to a minimum altitude of 18,500 feet. Seven subjects in the SUMMIT group attained a maximum altitude of 22,130 feet.

Progress: Energy intake from the high carbohydrate (CHO) diet sources averaged 67% over the study. Mean energy intake for the SUMMIT group fell from  $2054 \pm 56$  to  $641 \pm 60$  kcal by day 5. Energy intake for the NON-SUMMIT group also declined consistently from day 1 to day 5, from  $2036 \pm 43$  to  $1043 \pm 88$  kcal. Mean weight loss for the 18 subjects was  $2.5 \pm 0.45$  kg. SUMMIT group lost an average of  $2.95 \pm 0.96$  kg. Though weight loss is a common problem in high altitude expeditions, the rate of weight loss in this study (0.49 kg/day) for five

C-118-89 (continued)

days was alarming. Feedback from subjects suggested that CHO entrees were unpalatable and unappetizing. Gastrointestinal distress and gas production were universal symptoms. Because caloric intake is the primary nutritional concern at altitude, dietary composition should be a secondary priority. The results of this study suggest that a high CHO diet may not be the best diet for high altitude expeditions.

# Detail Summary Sheet

Date: 6 Aug 90 Proj No: C-120-89 Status: Terminated  
 Title: LCSG 881 - A Randomized Phase II Study of Preoperative Therapy for  
 Patients with Technically Unresectable Non-Small Cell Lung Cancer

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator James G. Wall, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Hem-Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To collect information regarding efficacy and toxicity of various preoperative treatment programs.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This study was terminated due to closure of the Lung Cancer Study Group.

# Detail Summary Sheet

Date: 6 Sep 90 Proj No: C-121-89 Status: Ongoing  
 Title: Acute Serum Potassium Elevation After Intravenous Hypertonic Contrast in Patients with Normal, Impaired, and Absent Renal Function

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator (vice Buchanan) Steven F. Gouge, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators:
Key Words:	Ronald Salmond, MAJ, MC David Slife, MAJ, MC Joseph Johns, MAJ, MC James Heironimus, Lt Col, USAF MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 11	
Total Number of Subjects Enrolled to Date: 11	
Date of Periodic Review 10 Sep 90	Results Continue

Objective(s): To determine if there is a significant elevation in serum potassium after intravenous hypertonic iodinated contrast and whether patients with impaired or absent renal function are at increased risk of more marked and persistent hyperkalemia.

Technical Approach: Subjects with normal renal function and chronic renal insufficiency will be enlisted from adult patients scheduled for nonemergent cardiac catheteriation and divided into three gorups. Group 1 will include patients with glomrulofiltration rate (GFR) 140-61 ml/min, Group 2 with GFR 60-10, and Group 3 with GFR <10. Precontrast blood samples will be drawn and collected by the principal investigator. Elevation in serum K after contrast within each group will be analyzed for significance. Assays plus plasma catecholamines will be performed

Progress: Recruitment of group 2 and group 3 patients has been slow.



# Detail Summary Sheet

Date: 7 Sep 90	Proj No: C-122-89	Status: Ongoing
Title: A Technique for the Growth of Epidermal Sheets Obtained from Patients Undergoing Reduction Mammoplasty		

Start Date: 31 Oct 89	Est Comp Date:
Principal Investigator Jerome C. Hill, CPT, MC	Facility Brookè Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators: Ronald E. Grimwood, Lt Col, USAF MC Larry E. Becker, COL, MC William K. Becker, LTC, MC David L. Danley, MAJ, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$31,500.00 (R&D)
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 10 Sep 90 Results Continue	

Objective(s): To establish a technique for isolating and growing epidermal sheets from cells obtained from patients undergoing reduction mammoplasty.

Technical Approach: Discarded skin was obtained from patients undergoing reduction mammoplasty. The epidermis was enzymatically separated from the dermis. Keratinocytes were isolated from the epidermis and seeded in 25 cm<sup>2</sup> cell culture flasks. The growth medium was Keratinocyte Growth Medium (KGM) which has been developed for the growth of keratinocytes. In approximately two weeks, the primary keratinocyte cultures were nearly confluent and were serially subcultured to expand the volume of cells.

When secondary cultures reached confluence, the cell medium was changed to Dulbecco's Modified Eagles' Medium containing 10% fetal calf serum. The change to a medium containing serum and a higher calcium concentration induced the keratinocytes to stratify into multi-layered sheets. These epidermal sheets were removed from the culture flask with Dispase, a neutral protease, and attached to petrolatum gauze. At this point the sheets could be used as skin grafts.

Progress: To date we have placed epidermal grafts on two patients. The first patient was a 5 year old boy with a diagnosis of junctional epidermolysis bullosa. This disease results in chronic skin erosions that are very resistant to conventional therapy. The grafting of this patient took place at Wilford

C-122-89 (Continued)

Hall USAF Medical Center. Epidermal allografts were derived from a skin biopsy from the patient's mother. We have grafted this patient a total of five times. He has had significant healing of his central facial erosions.

The second patient was from the ISR. He was a civilian burn victim with 2nd and 3rd degree burns. We provided ISM with five epidermal autografts of approximately 250 cm<sup>2</sup> surface area. The grafts were left untouched for two weeks. After removal of the petrolatum gauze it was determined that the grafts did not take. We received a skin biopsy from a second burn patient but the cell cultures became contaminated and had to be discarded. Further attempts to provide the ISR with epidermal autografts for burn patients may take place in the future.

# Detail Summary Sheet

Date: 6 Sep 90 Proj No: C-125-89 Status: Ongoing  
 Title: Phase II Trial of High-Dose Busulfan and Cyclophosphamide with Autologous Bone Marrow Transplantation in Metastatic Breast Cancer

Start Date: 31 Oct 89	Est Comp Date:
Principal Investigator Patrick W. Cobb, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Hem-Oncology	Associate Investigators: Richard O. Guidice, MAJ, MC Svetislava J. Vukelja, MAJ, MC Robert G. Whiddon, Jr., LTC, MC Barbara Reeb, MT Rory Duncan, SSG
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 10 Sep 90 Results Continue	

Objective(s): To study the effects of high dose chemotherapy and autologous bone marrow transplantation on women with metastatic breast cancer.

Technical Approach: Ten to twenty women from 18-65 years of age who have metastatic breast cancer of cytotoxic or hormonally-resistant disease will be treated with high-dose cyclophosphamide and busulfan. The primary endpoints for this pilot study will be the complete remission rate and duration of remissions, as compared to other recent high-dose chemotherapy and ABMT regimens for breast cancer. If this regimen appears to be at least as active as published regimens and is well-tolerated, then a third drug will be added in an attempt to increase efficacy in a subsequent phase I study.

Progress: Four patients have been enrolled thus far. All patients have tolerated the protocol well, and all survived the transplantation procedure. There have been two partial remissions, one complete remission, and one patient did not respond. We plan to continue the protocol as written, but will soon send an addendum changing the mode of busulfan administration.

# Detail Summary Sheet

Date: 22 Aug 90 Proj No: C-128-89 Status: Ongoing  
 Title: In vivo Validation of Catheter Mounted Piezoelectric Phonocardiographic Transducer

Start Date: 31 Oct 89	Est Comp Date:
Principal Investigator Randolph Modlin, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: James K. Gilman, MAJ, MC J. Mark Moody, Jr., LTC, MC Bernard J. Rubal, Ph.D.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 12 Sep 90 Results Continue	

Objective(s): To compare direct intracardiac phonocardiographic recordings to recordings derived from micromanometric pressure transducers.

Technical Approach: Piezoelectric phonocatheters will be used on 50 patients undergoing right and left heart catheterization to record intracardiac sound for comparison with signals derived from micromanometric pressure transducers. In vitro evaluation suggests that the piezoelectric phocatheter possesses improved frequency response characteristics and better signal-to-noise ratio than data obtained from the standard Millar pressure transducer. In this preliminary study, a spectrum of cardiac pathology is sought to demonstrate the efficacy of the new catheter and identify different pathologic states that might prove fruitful for further investigation.

Progress: Technical difficulties with obtaining the catheter and configuring the cath lab have delayed initiation of enrolling patients. At this point, one patient has been enrolled. Data obtained is undergoing analysis for quality. It is hoped that the number of patients entered in the study will increase. No complications, misadventures or adverse reactions have arisen. No new risks have been identified.

# Detail Summary Sheet

Date: 18 Sep 90	Proj No: C-3-90	Status: Ongoing
Title: Differences in Response to Thiazide-Induced Hyponatremia by Gender		

Start Date 7 Dec 89	Est Comp Date:
Principal Investigator (vice Abbott) Robert Oglesby, CPT	Facility Brooke Army Medical Center
Dept/Svc Dept of Medicine, Nephrology Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 5	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review n/a	Results

Objective(s): To investigate the differences in response to water challenge testing by sex before and after administration of hydrochlorothiazide in a controlled, prospective fashion. This is to determine if recommendations for changing dosages or even changing drug therapy in the initiation of diuretic therapy is necessary for a wide range of outpatients in the U.S.

Technical Approach: Ten men and ten women, age 55 and above, with no concurrent hypertension or diabetes will be studied. Baseline blood tests will be drawn for serum sodium and potassium as well as thyroid function tests and serum cortisol levels. If these are normal, the patients will undergo a baseline water challenge test in which they drink 20ml/kg of ideal body weight of fresh water followed by hourly urine samples for urine electrolytes and osmolality. Before the water load and after four hours, blood samples will be drawn for serum sodium, potassium, antidiuretic hormone, prolactin, and possibly diuretic levels and atrial natriuretic factor.

Progress: We are preparing the study patients for the actual study procedure at this time.

# Detail Summary Sheet

Date: 17 Oct 90 Proj No: C-4-90 Status: Ongoing  
 Title: Utilization of Acute Bronchodilator Resonances in Chronic Obstructive Pulmonary Disease to Predict Relative Efficacy of Individual Agents

Start Date 7 Dec 89	Est Comp Date:
Principal Investigator Mark D. Peacock, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Pulmonary Disease/Critical Care Serv.	Associate Investigators: James E. Johnson, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 23	
Total Number of Subjects Enrolled to Date: 23	
Date of Periodic Review	Results

Objective(s): The objective of this study is to determine if testing the acute bronchodilator response of stable patients with chronic obstructive pulmonary disease (COPD) utilizing a panel of inhaled agents can correctly predict which agent will be most efficacious in improving the patient's exercise tolerance, dyspnea, and pulmonary function tests.

Technical Approach: Ten patients with stable COPD will be recruited. After collection of baseline demographic data, each patient will complete a dyspnea questionnaire, perform a 12-minute walking test, and undergo a series of spirometries. Pulmonary function tests will be performed before and after administration of 4 or 5 different inhaled medications on 5 consecutive days.

Progress: Eighteen of twenty-three patients have completed the protocol. Two dropped out secondary to COPD exacerbations, two because of inconvenience, and one due to a new diagnosis of metastatic cancer. Preliminary review of the remaining 18 patients reveals that the FEV<sub>1</sub>, ABG's, 12 minute walk and dyspnea scores are slightly better after four weeks of the "better" inhaler, but not statistically significant and actually not clinically significant.

# Detail Summary Sheet

Date: 29 Oct 90	Proj No: C-6-90	Status: Ongoing
Title: Evaluation of Hypophosphatemia in Chronic Obstructive Pulmonary Disease		

Start Date 9 Dec 89	Est Comp Date:
Principal Investigator James Brassard, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine	Associate Investigators: Gregg T. Anders, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): Hypophosphatemia has been shown to impair diaphragmatic contractility and precipitate acute respiratory failure. Phosphate depletion has also been shown to impair leukocyte function which may predispose chronic pulmonary patients to acute infection.

Technical Approach: Pulmonary Disease Clinic files will be reviewed and patients with current baseline spirometry and chemistry profiles obtained within 24 hours of one another will be considered eligible. Serum Inorganic Phosphate will be determined from the chemistry profiles with HypoP classified as mild, moderate or severe. The prevalence of HypoP in COPD patients will be determined and compared to normal subjects as demonstrated by baseline spirometry.

Progress: No correlation between obstructive lung disease and reduced serum phosphate levels was demonstrated. The prevalence of hypophosphatemia in COPD outpatient setting (2/42 =4.8%) appears to reflect inpatient estimates of 2-5% from previous studies. The significant association of increasing age and reduced serum phosphate levels suggests a more prominent mechanism for phosphate depletion in the aged, although such a correlation with the older COPD patients in Group II was not present. Certain aspects of this study require further review. Hypophosphatemia is often a late finding in phosphorus depletion, usually preceded by hypophosphaturia and hypercalciuria. Also inorganic phosphate measurements may not be as accurate a reflection of true intracellular organic phosphate stores as would values such as RBC ATP of 2.3-DPG. A diurnal variation of serum phosphate levels has been described, and an evaluation of this parameter was not included in this study. More thorough research into these issues in ambulatory COPD patients is needed.

# Detail Summary Sheet

Date: 25 Sep 90 Proj No: C-10-90 Status: Ongoing  
 Title: Hemodynamic Tolerance to Hemodialysis in Critically Ill Patients: A Prospective Comparison of Sorbsystem Bicarbonate Hemodialysis and Single-Pass Bicarbonate Hemodialysis.

Start Date 7 Dec 89	Est Comp Date:
Principal Investigator Ronald Salmond, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Nephrology Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): This randomized prospective study is designed to compare hemodynamic tolerance to sorbent system-bicarbonate hemodialysis (SS-B), and single pass-bicarbonate hemodialysis (SP-B) in critically ill patients with acute renal failure (ARF) and examine the condition of arterial and mixed venous blood gases during SS-B and SP-B.

Technical Approach: Patients will be randomized utilizing a random number table into being dialyzed on four consecutive dialyses with alternating sorbent system bicarbonate and single pass bicarbonate dialysates. Body weight will be monitored continuously by use of electronic bed scale. Intravascular volume expansion with 0.9% saline will be used to maintain a systolic arterial pressure of at least 100 mmHg during hemodialysis.

Progress: Initiation of this study is pending approval to accept a research grant from the National Kidney Foundation of Texas.



# Detail Summary Sheet

Date: 19 Jul 90 Proj No: C-13-90 Status: Completed  
 Title: A Review of Empyema Thoracis

Start Date 2 Jan 90	Est Comp Date:
Principal Investigator Michael J. Morris, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/General Medicine	Associate Investigators: J. William Kelly, MAJ, MC
Key Words: Empyema Thoracis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To review cases of empyema thoracis within the last ten years to evaluate recent trends in antibiotic treatment, surgical intervention and their relationship to outcome of therapy. To determine if the recent advent of broad spectrum antibiotics have positively influenced the outcome of empyema.

Technical Approach: Forty cases of empyema thoracis which presented between 1985 and 1990 at Brooke Army Medical Center were retrospectively reviewed.

Progress: The predominant cause was postpneumonic (42.5%) followed by cancer-related (17.5%), posttraumatic (17.5%), postsurgical (15.0%), and intraabdominal processes (7.5%). Streptococcus pneumoniae was isolated in the majority of empyemas secondary to community-acquired pneumonias, but there was a large percentage of negative cultures. The mortality in this group was low, correlating with a recent study of this specific cause of empyema. Cancer-related empyemas had a high mortality rate of 75% and accounted for most of the 20% overall mortality. Gram negative bacilli and Staphylococcus aureus were primarily isolated from the cancer, trauma, and surgery patients. Drainage of the pleural space was accomplished by tube thoracostomy in 90% of the patients and only 25% underwent decortication for incomplete drainage or persistent symptoms. This proved

C-13-90 (continued)

to be an effective means of treatment and there was no mortality when complete drainage was accomplished. Underlying diseases did not affect outcome except in those patients with an active malignancy. This was also shown with age as there was no relationship to mortality. Symptoms are nonspecific but most commonly include fever (53%), chest pain (38%), cough (20%), and dyspnea (15%). Empiric antibiotic choice was appropriately made according to the underlying cause and did not affect outcome. The role of newer cephalosporins, monobactams, penicillins, and quinolones was reviewed and did not prove to be significant in improving treatment. Finally, the criteria to determine infected pleural effusions by fluid chemistries (pH, LDH, and glucose) proved to be reliable.

# Detail Summary Sheet

Date: 18 Sep 90 Proj No: C-14-90 Status: Ongoing  
 Title: The Role of Immediate Versus Delayed Treatment in Urgent Hypertension:  
 A randomized, prospective trial.

Start Date 18 Jan 90	Est Comp Date:
Principal Investigator Timothy P. Endy, M.D., MPH, CPT	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 15	
Total Number of Subjects Enrolled to Date: 15	
Date of Periodic Review n/a	Results

Objective(s): The objective of this randomized, prospective trial is to determine the efficacy of immediate versus delayed therapy in lowering the blood pressure of urgent hypertensives. Blood pressure control at 24 and 48 hours and seven days will be assessed as well as differences in morbidity and mortality.

Technical Approach: Following routine blood tests, physical examination, EKG and chest x-ray, patients will be randomized into one of two groups. One group will receive Procardia every 8 hours or Enalapril 10 mg per day. The other group will be given Procardia 10 mg under the tongue every 30 minutes or until the blood pressure is reduced to a lower level. After the blood pressure is reduced, either Procardia, 10 mg every 8 hours, or Enalapril 10 mg per day will be given. Patients will be evaluated at 24 and 48 hours and again 7 days after entering the study between those treated immediately versus those given delayed therapy.

Progress: So far we have entered 15 patients into the study with our original goal being 40 patients. Tentatively we plan to see if 20 patients will allow us to reach clinical statistical significance given the number of blood pressure readings available from our ambulatory blood pressure monitoring.

The only complication so far has been one individual who was noncompliant on her medications the week prior to being seen and entered into the study. After entering the study she not only took the protocol medication but also strictly

C-14-90 (continued)

adhered to her previous drug regimen. On follow-up at 24 hours, she was having symptoms of light headedness and had a systolic blood pressure of less than 100. She required a reduction in her original blood pressure medications and has done well since. Otherwise there have been no complications or problems from the study.

# Detail Summary Sheet

Date: 26 Aug 90	Proj No: C-21-90	Status: Ongoing
Title: A Double Blind Clinical Evaluation of the Safety and Efficacy of Fenticonazole Cream (2% Fenticonazole Nitrate) in the Treatment of Tinea Pedis.		

Start Date 25 Jan 90	Est Comp Date:
Principal Investigator Larry E. Becker, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 40	
Total Number of Subjects Enrolled to Date: 40	
Date of Periodic Review	Results

Objective(s): To determine the safety and efficacy of Fenticonazole Cream in the treatment of tinea pedis.

Technical Approach: Approximately 40 patients will be selected for participation in this study. Male and female patients eighteen years of age and older with clinical signs of moderate to severe tinea pedis will be treated for four weeks once daily with vehicle controlled placebo or active agent. Follow-up visits at 2 and 4 weeks and again at 6 weeks (2 weeks after completing treatment) will be used to evaluate clinical and laboratory evidence of success of therapy.

Progress: Forty patient have been enrolled in the study. Twenty-eight patients remain in study without side effects. Nine patients are being followed for scheduled visits, and three patients have been dropped from the study.

One patient was dropped from the study after being admitted to the VA Hospital for alcohol abuse treatment not related to the study. One patient was dropped after approximately one week due to a significant clinical flare in the severity of tinea pedis attributed to lack of control by the study medication. The treatment code packet for this patient was broken to determine if this flare was a side-effect of the medication or a flare of his disease. The patient was on placebo and the tissue scraping for examination was positive for fungus confirming the clinical impression of a flare of the underlying tinea. The patient was started on an approved antifungal and subsequently markedly improved. One patient failed to return for the scheduled 6 week follow-up visit.

C-21-90 (continued)

Data collection is not complete and blinded code of study medication versus placebo is not available except for the one patient in which the code was broken. Upon completion of the study a final report will be submitted.

# Detail Summary Sheet

Date: 26 Sep 90      Proj No: C-22-90      Status: Ongoing  
 Title: Phase II Clinical Trial of Anagrelide in Thrombocytosis of Myelo-  
 proliferate Disorders (70014), Compassionate Use.

Start Date 25 Jan 90	Est Comp Date:
Principal Investigator (vice Foulke) Terry R. Jenkins, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Hematology-Onc.	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review _____ Results _____	

Objective(s): To determine the ability of anagrelide to effectively reduce platelet numbers in patients with thrombocythemia, to determine the dose of anagrelide which would be required to reduce platelet numbers and the dose needed to maintain them at or close to normal levels and to evaluate the safety of this compound.

Technial Approach: Three patients have been enrolled on this study. Therapy is in accordance with the study protocol.

Progress: An additional patient was entered on this study who later withdrew because of gastrointestinal toxicity. The original two patients continue to do well on treatment.

# Detail Summary Sheet

Date: 18 Sep 90      Proj No: C-23-90      Status: Ongoing  
 Title: Open Label Dose Tolerance Study of Intravenous Ilmofofosine Administered Every Twenty-eight Days to Patients with Cancer Refractory to Standard Treatment, Phase I.

Start Date 16 May 90	Est Comp Date:
Principal Investigator James G. Wall, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Hematology-Oncology Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 6	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review n/a	Results

Objective(s): 1) To determine the maximum tolerated dose of ilmofofosine when administered intravenously once every twenty-eight days. To describe the toxicity of ilmofofosine when administered intravenously on the schedule described above. 2) To describe the pharmacokinetics of ilmofofosine and metabolite when administered intravenously. To evaluate anti-tumor activity if observed.

Technical Approach: Therapy will follow the schema in the drug company protocol.

Progress: We continue to accrue patients to this protocol in conjunction with the University of Texas Health Science Center at San Antonio. There have been no serious adverse reactions to this drug. At the current dose level it continues to be a very well-tolerated drug. We believe we are nearing a dosage level which might be associated with myelosuppression.



# Detail Summary Sheet

Date: 17 Oct 90 Proj No: C-24-90 Status: Ongoing  
 Title: Induction of TNFa and IL-1 in Human Tuberculosis.

Start Date 5 Feb 90	Est Comp Date:
Principal Investigator (vice Smith) Keith A. Konkol, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Infectious Diseases Service	Associate Investigators: J. William Kelly, MAJ, MC C. Kenneth McAllister, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$14,300.00 (R&D)
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): The objective of this study is to determine the extent of tumor necrosis factor-alpha (TNF-a) and interleukin-1 (IL-1) production associated with human tuberculosis. Peripheral blood monocyte cells (PBMC) from patients with positive purified protein derivative (ppd) skin reactions or active tuberculosis will be compared with healthy controls (PPD negative) by in vitro stimulation with mycobacterial antigens and killed Mycobacterium tuberculosis and the concurrent production of TNF-a and IL-1 measured by ELISA.

Technical Approach: Patients and healthy controls (staff volunteers) will be phlebotomized approximately 50 ml of blood by peripheral venipuncture. In vitro antigen stimulation of PBMC and measurement of TNF-a and IL-1 production by ELISA will be performed.

Progress: No reportable data are available at this time due to change in principal investigators because of Operation Desert Shield.

# Detail Summary Sheet

Date: 26 Sep 90 Proj No: C-28-90 Status: Completed  
 Title: Determination of the Genesis of the C-wave

Start Date 13 Feb 90	Est Comp Date:
Principal Investigator Landon Wellford, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Joseph P. Johns, MAJ, MC J. Mark Moody, Jr., LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 8	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review	Results

Objective(s): To confirm the genesis of the C-wave in the jugular-venous pulsation tracing.

Technical Approach: Eight patients in sinus rhythm with normal right heart pressures without valvular disease or prior infarction were studied with a multi-sensor, high-fidelity catheter. Sensors were positioned in the right atrium (RA), SVC, and right internal jugular vein, and simultaneous surface tracings were obtained from the internal jugular vein and carotid artery. M-mode echo and phonocardiograms were performed to index timing of tricuspid valve closure (TVC) to the ECG R wave.

Progress: The C wave occurred in the RA 5 msec (range 0-38) after TVC. It is propagated to the jugular veins at 2.4 meters/sec (m/s). The V and A wave velocities were 1.5 and 2.5 m/s, respectively. The surface pulse tracings closely matched the internal pressure recordings with an average 15 msec delay.

We conclude that the C wave is venous in origin, resulting from closure of the tricuspid valve, and that jugular venous waves propagate at 1.5 to 2.5 m/s.

# Detail Summary Sheet

Date: 18 Sep 90 Proj No C-29-90 Status: Ongoing  
 Title: Epsilon-aminocaproic acid mouthwash therapy for dental extractions of lower molar teeth in normal subjects: A double blind controlled trial.

Start Date 13 Feb 90	Est Comp Date:
Principal Investigator (vice Cadiz) Karen Bowen, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/General Medicine	Associate Investigators: William P. Mills, Jr., LTC, DC Andrew A. Vorana, LTC, DC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 125	
Total Number of Subjects Enrolled to Date: 125	
Date of Periodic Review	Results

Objective(s): To conduct a randomized, double blind, placebo controlled trial to evaluate the effect of low-dose EACA as a mouthwash on the incidence of dry socket in the general population.

Technical Approach: Patients will be randomized to receive either EACA solution or a placebo (the same solution without EACA). This solution will be used to wash the extraction site and soak the dressing placed at the end of the procedure. A supply of the solution will be given along with instructions to use two tablespoons to swish in the mouth for 2 minutes. This will be done 6 hours after the procedure and then three times a day for 4 days. Three days and seven days after the procedure, the participant will be contacted to determine if there is any pain, how well they are able to eat, and any other problems they may be having. If there is any indication of dry socket they will be asked to return.

Progress: No reportable data are available at this time.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-31-90 Status: Ongoing  
 Title: Gastric Hyposecretion in Patients with HIV-1 Infection

Start Date 13 Feb 90	Est Comp Date:
Principal Investigator Richard T. Shaffer, CPT	Facility Brooke Army Medical Center
Dept/Svc Department Medicine/Gastroenterology	Associate Investigators: Lawrence HaHatte, M.D. J. William Kelly, MAJ, MC Francis E. Peluso, MAJ, MC Eddie C. Starnes, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 23	
Total Number of Subjects Enrolled to Date: 34	
Date of Periodic Review	Results

Objective(s): To determine if gastric secretory failure, known to occur frequently in patientss with AIDS, is present in earlier stages of HIV infection.

Technical Approach: Approximately 70-80 subjects will be required, consisting of 15-20 healthy age-matched individuals as controls and 50-60 patients with HIV infection. After an overnight fast, basal acid output (BAO), maximum acid output (MA), and peak acid output (PAO) will be determined using standard gastric analysis techniques.

Progress: To date 34 subject shave completed the protocol and are deemed adequate. Six additional subjects had been enrolled but will be excluded from analysis secondary to incomplection of the gastric acid collection, technical difficulty, or fulfilled the exclusion criteria.

BAO and MAO in all HIV patients were similar to controls. PAO was increased in all HIV patients compared to controls. Using ANOVA there was no significan difference in BAO, MAO, and PAO between controls.

Conclusion: While gastric acid hyposecretion may exist in AIDS patients, it does not appear to be present in early HIV infeciton. Although PAO was higher in the combined HIV group, it did not approach levels of hypersecretion. No significant impairment in acid secretion was associated with progression of HIV disease.

# Detail Summary Sheet

Date: 25 Sep 90 Proj No: C-39-90 Status: Ongoing  
 Title: A Comparison of Intravenous Diazepam and Midazolam on Venous Complications After Endoscopic Procedures.

Start Date 12 Mar 90	Est Comp Date:
Principal Investigator John G. Carrougner, CPT	Facility Brooke Army Medical Center
Dept/Svc Gastroenterology Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 120	
Total Number of Subjects Enrolled to Date: 120	
Date of Periodic Review	Results

Objective(s): To evaluate the incidence of phlebitis, thrombophlebitis and thrombosis after intravenous administration of diazepam and midazolam. The study is designed to obtain information which can be used to minimize venous complications post IV sedation after endoscopic procedures.

Technical Approach: There will be four patient groups: a) Midazolam/Demerol vs Diazepam/Demerol and b) Hand dorsum vs forearm (excluding the antecubital area). A total of 120 patients will be required with 30 patients in each group. One half the patients will receive diazepam/demerol and one half will receive medazolam/demerol. Onehalf will have an intravenous catheter placed into a vein in the forearm and oth other half will have it placed into a vein in the hand. Follow-up telephonic interviews will be completed at 3-4 days, 10-12 days, and 20-21 days.

Progress: Data has been collected on 120 patients which is in the process of being interpreted. More than 300 follow-up telephone calls have been completed.

# Detail Summary Sheet

Date: 26 Sep 90 Proj No: C-40-90 Status: Ongoing  
 Title: Prostaglandin Excretion of Radiocontrast Induced Acute Renal Failure.

Start Date 12 Mar 90	Est Comp Date: :
Principal Investigator William G. Wortham, MAJ	Facility Brooke Army Medical Center
Dept/Svc Nephrology Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To determine if prostaglandins are diminished in response to radiocontrast administration in the human subject. Further to determine if this decrement, if noted, correlates with a change in renovascular resistance, renal blood flow and/or creatinine clearance during the acute period surrounding radiocontrast administration.

Technical Approach: Participants will be admitted 24 hours prior to cardiac catheterization for collection of a 24-hour urine sample for sodium and prostaglandin metabolites, thromboxane B2 and 24-hour creatinine. In addition, they will undergo a nuclear determination via plasma clearance, I<sup>131</sup> Hippuran and DTPA to determine renal blood flow as well as as GFR via radionuclide study. 4-6 hours prior to catheterization, they will receive half-normal saline at approximately 125 cc/hour if not contraindicated by volume status. At cardiac catheterization, a determination of central venous pressure will be necessary. Immediately after contrast administration, a second spot renin and catechol determination will be made. After cardiac catheterization a 24-hour urine will be collected for prostaglandin metabolites and sodium and creatinine as well as routine serum creatinine and electrolytes. An I<sup>131</sup> Hippuran and DTPA for determination of renal plasma flow and glomerular filtration will be obtained 24 hours post cardiac catheterization.

Progress: No patients have been entered on this study.

# Detail Summary Sheet

Date: 28 Aug 90      Proj No: C-46-90      Status: Ongoing  
 Title: Development of Autologous in vitro Composite Skin Graft Suitable for Grafting to Burn Wounds.

Start Date 27 Mar 90	Est Comp Date:
Principal Investigator James C. Hill, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators: Charles W. Lewis, COL, MC Eleanor Ayala, Medical Technologist
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To develop a coposite in vitro skin graft suitable for transplantation to patients with burn injury.

Technical Approach: Initially cells will be isolated from normal skin obtained from plastic surgery procedures. A collagen matrix optimized for our use will be provided by Dr. Frederick H. Silver. The coposite graft will be analyzed by light and electron microscopy and immunofluorescent staining for comparison to normal skin. Once the technique has been established, we will enter into a collaborative research study with the Institute of Surgical Research to obtain cells from skin of burn patients to prepare composite grafts.

Progress: This study has been put on hold awaiting funding from the Medical Research and Development Command.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-50-90 Status: Ongoing  
 Title: Phase I Study of Intraperitoneal Cisplatin and Mitoxantrone.

Start Date 27 Mar 90	Est Comp Date:
Principal Investigator Don W. Shaffer, MAJ	Facility Brooke Army Medical Center
Dept/Svc Hematology-Oncology Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1.1 To determine the feasibility of administering a combination of mitoxantrone and cisplatin to the peritoneal cavity of patients with peritoneal dissemination of cancer or malignant ascites. 1.2 To characterize the hematological and non-hematological toxicity of cisplatin and mitoxantrone after intraperitoneal administration. 1.3 To evaluate patients for evidence of antitumor activity after the intraperitoneal administration of cisplatin and mitoxantrone. 1.4 To establish the maximum tolerated dosages of cisplatin and mitoxantrone when administered in combination to the peritoneal cavity.

Technical Approach: Mitoxantrone will be given every three weeks by abdominal catheter over 1-2 hours. Cisplatin will be given every three weeks along with Mitoxantrone. These treatments will be repeated every three weeks provided no severe side effects occur and the tumor does not increase in size. The responsiveness of the tumor to treatment will be assessed every three weeks on study.

Progress: No patients from BAMC have been enrolled. Twelve of planned 18 patients have been enrolled at UTHSC in the last 12 months.



# Detail Summary Sheet

Date: 16 Oct 90 Proj No: C-52-90 Status: Ongoing  
 Title: An Open Label Study Regimen of Videx™ (2',3'-Dideoxyinosine,ddi) in Patients with Acquired Immunodeficiency Syndrome (AIDS) Exhibiting Significant Deterioration while Taking Zidovudine (Retrovir®).

Start Date 24 Apr 90	Est Comp Date:
Principal Investigator J. William Kelly, MAJ	Facility Brooke Army Medical Center
Dept/Svc Infectious Disease Service	Associate Investigators: Craig T. Smith, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review	Results

Objective(s): To make ddI available to many patients with AIDS who are clinically deteriorating on AZT and cannot enter the Phase II ddI program due to protocol exclusion or geographic location.

Technical Approach: Treatment will consist of a reconstituted oral dose of ddI prepared according to instructions and administered every 12 hours on an empty stomach.

Progress: No complications. The one patient enrolled on this study has taken medication for four months without difficulty.

# Detail Summary Sheet

Date: 16 Oct 90                      Proj No: C-53-90                      Status: Ongoing  
 Title: A Treatment IND (Investigational New Drug) Protocol for the Use of Videx™ in Patients with Acquired Immunodeficiency Syndrome (AIDS) or AIDS Related Complex (ARC) who are tolerant to Zidovudine (Retrovir®).

Start Date 24 Apr 90	Est Comp Date:
Principal Investigator J. William Kelly, MAJ	Facility Brooke Army Medical Center
Dept/Svc Infectious Disease Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review _____ Results _____	

Objective(s): To make ddI available to many patients with HIV infection (suffering) from ARC or AIDS who have 1) have developed intolerance to AZT and 2) cannot enter the Phase II ddI program due to protocol exclusion or geographic location.

Technical Approach: Treatment will consist of a reconstituted oral dose of ddI prepared according to instructions and administered every 12 hours on an empty stomach.

Progress: One patient was enrolled for persistent thrombocytopenia thought to be due to AZT, but platelet count failed to rise when AZT was stopped and ddI was never given.

# Detail Summary Sheet

Date: 17 Oct 90      Proj No: C-55-90      Status: Ongoing  
 Title: Coronary Laser Angioplasty

Start Date 24 Apr 90	Est Comp Date:
Principal Investigator William R. Condos, LTC	Facility Brooke Army Medical Center
Dept/Svc Cardiology Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To study the safety and efficacy of coronary laser angioplasty with the LASTAC System.

Technical Approach: Patients will first undergo routine cardiac catheterization. If clinically indicated, percutaneous transluminal coronary angioplasty (PTCA) will be offered. If unable to cross the lesion with the wire or balloon, laser ablation will be attempted, and if successful, PTCA may then be continued.

Progress: No progress has been made due to failure to obtain rental of the LASTAC Systsem. A request is being submitted for purchase as a MEDCASE item.

# Detail Summary Sheet

Date: 28 Aug 90 Proj No: C-58-90 Status: Terminated  
 Title: A Double-Blind Prospective Randomized Evaluation of the Efficacy and Safety of Isepamicin Versus Amikacin in Bacterial Infections.

Start Date 1 May 90	Est Comp Date:
Principal Investigator Keith A. Konkol, CPT	Facility Brooke Army Medical Center
Dept/Svc Infectious Disease Service	Associate Investigators: C. Kenneth McAllister
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): This study is a randomized double-blind evaluation of the efficacy and safety of isepamicin versus amikacin with and without concomitant antibiotics in the treatment of culture-documented enfections caused by susceptible gram negative bacteria. In addition to comparing the efficacy and safety of isepamicin versus amikacin, a second objective will be to compare the efficacy and safety of once daily dosing with isepamicin to that to twice daily dosing in the same infections.

Technical Approach: Study terminated before patient enrollment started.

Progress: When the protocol was submitted to the FDA questions were raised concerning the design of the study. Specifically, the FDA would not accept a multi-indications study. It was the company's opinion that a large multi-center study of patients with a variety of bacterial infections is the most appropriate method for analyzing the validity of the once daily dosing of aminoglycosides concept. Therefore, the protocol was terminated.

# Detail Summary Sheet

Date: 27 Oct 90 Proj No: C-59-90 Status: Ongoing  
 Title: Eprex™ (r-HuEPO) Treatment Program for Anemia in AIDS Patients.

Start Date 1 May 90	Est Comp Date:
Principal Investigator J. William Kelly, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Infectious Disease Service	Associate Investigators: Craig T. Smith, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To provide Eprex for the treatment of anemia in AIDS patients.

Technical Approach: Eligible patients will receive 4,000 units of EPREX per day for six days. No EPREX will be administered on the seventh day. This weekly dose of 24,000 units will be continued for twelve weeks. The target hematocrit is 38-40%.

Progress: No patients have been entered on this study.

# Detail Summary Sheet

Date: 27 Sep 90 Proj No: C-60-90 Status: Completed  
 Title: Initial Operational Test and Evaluation of the Schistosome Topical Antipenetrant (TAP).

Start Date 1 May 90	Est Comp Date: 5 Jul 90
Principal Investigator Larry E. Becker, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators: John O'Brien, ITC, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 68	
Total Number of Subjects Enrolled to Date: 68	
Date of Periodic Review	Results

Objective(s): The broad objective of The Surgeon General, Department of the Army, in undertaking the clinical study of the 1% Niclosamide Lotion is to provide military personnel with a prophylactic agent to prevent schistosome infections. This lotion, when applied every 72 hours, should act as a barrier by killing schistosome cercariae to prior to their penetration of the skin.

Technical Approach: Medics in the Advanced Individual Training at the Academy of Health Sciences comprised the study group. For purposes of testing whether the TAP caused an oily feeling on the skin or made the skin slippery, a 7 point rating scale was provided prior to applying the solution. Next the TAP was applied and how oily the arms and hands felt was recorded on a similar scale. A similar rating was used to record how slippery the arms and hands felt with and without TAP. Participants were asked to record whether or not the odor caused nausea or was otherwise unacceptable.

Progress: 1. Solicitation for volunteers to participate in the study was done at the Academy of Health Sciences, 19 June 1990. Approximately 120 91A medic trainees were briefed concerning the study. After questions and answers, consent forms were completed by 86 volunteers.

2. Sixty-eight total study volunteers were enrolled in and completed the one day study on 2, 3, or 5 July 1990.

3. No evidence of any chapping, irritation, rash, or erythema was observed secondary to the study medication. No evidence of skin or clothing discoloration or staining was observed. One study participant on 3 July was seen on

C-60-90 (continued)

5 July after he developed poison ivy dermatitis on his right antecubital fossa and posterior to his right ear. This was not related to his study medication application on his left forearm.

4. General Observations.

a. No side effects of the study medication were observed on the 19 volunteers studied on 2 July.

b. Eight of the 29 participants studied on 3 July volunteered information during their exit examination that they noticed decreased sweating on the forearm treated with TAP. Seventeen patients stated they did not notice any difference in sweating. Four participants were not queried regarding sweating.

c. Two of the 20 volunteers studied on 5 July related they noticed decreased sweating on the TAP treated forearm. Both of these patients were in MOPP 4 status for 10 minutes, and one stated his treated arm felt cool even though he could see no sweating and his treated arm didn't sweat as much as his non-treated arm. Eighteen patients stated they did not notice any difference in sweating (14 of these were in MOPP 4 for 10 minutes also).

d. Unit rosters were checked and the volunteers who did not observe sweating were from various platoons in different areas of the barracks.

e. No direct observations of decreased sweating were observed but were reported by the volunteers after the fact. Sweating observations were not part of the initial study design.

5. Recommendations. Although there were no signs of any irritation from the TAP, the impact of the total body application of the agent and the possible decreased sweating has serious potential. I recommend that this be studied further with a prospective approach and methods to measure sweating, even as simple as starch-iodine documentation.

# Detail Summary Sheet

Date: 18 Sep 90 Proj No: C-63-90 Status: Ongoing  
 Title: Comparison of Adenosine, Dipyridamole, and Dobutamine Stress Echocardiography

Start Date 15 May 90	Est Comp Date:
Principal Investigator Timothy Martin, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: John Seaworth, LTC, USAF MC Joseph Johns, MAJ, MC Lawrence Pupa, MAJ, MC William Condos, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 32	
Total Number of Subjects Enrolled to Date: 32	
Date of Periodic Review	Results

Objective(s): To compare the ability of adenosine (AD), dipyridamole (DI), and dobutamine (DO) echocardiography to detect coronary vascular disease and compare the incidence and degree of adverse effects following adenosine, dipyridamole and dobutamine administration.

Technical Approach: We compared AD, DI, and DO stress echo in 32 patients. Each received intravenous AD, DI, and DO in a single-blind random order. Two dimensional echocardiography was positive if abnormal wall motion was present at rest or during infusion. Coronary angiography was performed within six weeks of testing. Eight patients had single vessel disease (stenosis >50%) and 16 patients had multivessel disease. Thirteen were taking beta blockers and 22 calcium channel blockers.

Progress: There was no difference in the ability of the drugs detect coronary disease ( $p > 0.05$ ). New or increased wall motion abnormalities occurred in 19 patients with DO, 13 with DI, and 9 with AD ( $p < 0.05$ ). The double product was significantly higher during DO infusion (16K vs 10K for AD and DI,  $p < 0.05$ ), but diagnostic ST changes were more common with DI (5) and AD (4) than DO (3). The infusion was stopped prematurely for severe symptoms or EKG changes in a few patients (DO-3, DI-3, AD-2), but no significant complications occurred with any drug. More patients preferred DO (16) than DI (11) or AD (5). In conclusion, although there were clinical differences between the drugs, each provided a safe, effective means for detecting coronary disease.



# Detail Summary Sheet

Date: 27 Sep 90 Proj No: C-65-90 Status: Ongoing  
 Title: Treatment of Chronic Cutaneous Ulcers with Cultured Epidermal Autografts

Start Date 15 May 90	Est Comp Date:
Principal Investigator Jerome C. Hill, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To determine the suitability of autologous kartinocyte grafts for the treatment of chronic cutaneous ulcers which have been refractory to standard therapy.

Technical Approach: Keratinocytes will be isolated from a small skin biopsy. The cells will be grown into stratified sheets and will be transplanted back to the patient from which the cells were obtained. The hypothesis to be tested: Can cutaneous ulcers which have not healed in spite of standard therapy be stimulated to epithelialize by using cultured epidermal autografts, even if the ulcer's base is the cortex of an underlying bone?

Progress: No patients have been entered in this study. It is anticipated that 3-5 patients per year will be eligible for enrollment.

### Detail Summary Sheet

Date: 18 Sep 90	Proj No: C-69-90	Status: Completed
Title: Incidence of Vancomycin-Induced Peritonitis in the United States		

Start Date 1 Jun 90	Est Comp Date:
Principal Investigator Steven F. Gouge, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: David I. Charney, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To attempt to quantify the incidence of chemical peritonitis (CP) occurring in patients on chronic peritoneal dialysis (PD) following intraperitoneal administration of vancomycin.

Technical Approach: Questionnaires were sent to 371 centers involved in the CAPD Registry, of which 164 (44%) were returned. Pertinent questions regarding the number of PD patients and the incidence of vancomycin-related peritonitis were asked.

Progress: Two centers had stopped CAPD and 19 never used IpV. Of 142 centers using IpV, 28 (20%) reported CP in association with IpV. Excluding 9 previously reported cases, there were 43 episodes in 41 patients, occurring with 0.5-2 g doses. Only one case was seen after use of Vancocin®, but 6 cases were seen after changing from Vancocin® to another brand. Cases were seen after treatment of exit site infections (21), other infections (11), and after a second dose for peritonitis (11). In 16 other cases, the diagnosis of CP was unclear. Due to CP, 5 centers no longer use IpV and 9 now use Vancocin® exclusively. Nineteen other centers have stopped using IpV due to reports of CP. The remaining 94 centers report no change in procedure due to such reports. Of the 94, 24 (26%) use Vancocin® exclusively and 36 (38%) use multiple brands.

We conclude that CP occurs frequently enough to be a clinical problem. Vancocin® appears to rarely cause CP. Many centers continue to use IpV despite reports of CP. These conclusions must be qualified by the nature of the study and the low response rate.

# Detail Summary Sheet

Date: 14 Sep 90      Proj No: C-70-90      Status: Ongoing  
 Title: Evaluation of Carboplatin and Mitoxantrone in Refractory or Relapsed  
 Non-Hodgkin's Lymphoma and Hodgkin's Disease: A Phase II Study

Start Date: 7 Jun 90	Est Comp Date:
Principal Investigator MAJ Don W. Shaffer	Facility Brooke Army Medical Center
Dept/Svc Department Medicine/Hem-Oncology	Associate Investigators: Timothy J. O'Rourke, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To determine in a Phase II, single-arm trial the activity and toxicity of carboplatin and mitoxantrone together as a salvage regimen for refractory or relapsed lymphoma (Hodgkin's and non-Hodgkin's) patient.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No patient has been enrolled on this study.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-71-90 Status: Ongoing  
 Title: High Dose Chemotherapy with Autologous Bone Marrow Support for Selected Advanced Solid Tumors

Start Date: 7 Jun 90	Est Comp Date:
Principal Investigator Svetislav J. Vukelja, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department Medicine/Hem-Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review	Results

Objective(s): To determine the toxicity, time to marrow reconstitution, response rate, and time to treatment failure of high-dose combination chemotherapy with carboplatin, etoposide, and cyclophosphamide followed by autologous marrow infusion in eligible patients with advanced metastatic solid tumors.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This 37-year-old white male with rhabdomyosarcoma was transplanted on this protocol on 2 July. He was discharged on day +34 in complete clinical remission.

# Detail Summary Sheet

Date: 29 Nov 90 Proj No: C-72-90 Status: Ongoing  
 Title: Nonobstructive Dysphagia: Evaluation by 24-Hour Ambulatory Esophageal Manometry.

Start Date 7 Jun 90	Est Comp Date:
Principal Investigator	Facility
Luis Canales, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Dept. of Medicine/Gastroenterology	Shailesch C. Kadakia, LTC, MC
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To evaluate patients with nonobstructive dysphagia by 24 hour ambulatory esophageal manometry.

Technical Approach: Patients meeting the criteria for inclusion will undergo 24-hour ambulatory esophageal manometry. After an overnight fast patients will report to the GI clinic where the manometry system will be zeroed and calibrated after attaching the manometry catheter to the recording box. The catheter will then be inserted into the esophagus, and the recording box set in the recording mode. The patient will be instructed regarding the use of the box over the next 24 hours and instructions to return the following morning for catheter removal.

Progress: None due to lack of funds to obtain the dual channel solid state motility catheter.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-73-90 Status: Ongoing  
 Title: Phase II Study of the Treatment for Lymphoma with Cytosan and VP-16 for  
 Cytoreduction Followed by High-Dose Chemotherapy Consisting of BCNU, ARA-C,  
 Cytosan and VP-16 (BACE) with Autologous Bone Marrow Transplant

Start Date: 7 Jun 90	Est Comp Date:
Principal Investigator MAJ Svetislava J. Vukelja	Facility Brooke Army Medical Center
Dept/Svc Department Medicine/Hem-Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review	Results

Objective(s): To examine the efficacy and toxicity of cytroeduction with  
 Cytosan and VP-16 followed by high-dose chemotherapy consisiting of BCNU, Ara-C,  
 Cytosan and VP-16 (BACE) with autologous bone marrow transplant for the treat-  
 ment of lymphomas.

Technical Approach: Patients meeting the criteria for inclusion will be treated  
 as outlined in the study protocol.

Progress: A 49-year-old white female with diagnosis of non-Hodgkin's lymphoma  
 was transplanted on 25 July. Patient expired on 25 August (day +25).  
 Preliminary autopsy report showed no evidence of lymphoma.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-74-90 Status: Ongoing  
 Title: The Incidence of Ambulatory Oxygen Desaturaton in Patients with Chronic Obstructive PULmonary Disease with and without Oxygen Therapy

Start Date 7 Jun 90	Est Comp Date:
Principal Investigator	Facility
Wayne T. Honeycutt, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Pulmonary	
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review	Results

Objective(s): To determine 24 hour ambulatory oxygen saturation monitoring if constant low flow oxygen therapy is an effective method of preventing oxygen desaturation and if oxygen desaturation occurs in patients without room air hypoxemia.

Approach: Phase I - Twenty-five patients meeting NOTT criteria for therapy will undergo ambulatory oxygen saturation monitoring for 24 hours. Patients will wear an ambulatory pulse oximeter and Holter monitor. The 24 hour pulse oximeter and Holter monitor recordings will be examined to determine if periods of desaturation are associated with dysrhythmia.

Phase II - Twenty-five patients with chronic COPD seen in the pulmonary clinic who have a  $PO_2$  less than 65 or FEV<sub>1</sub> < 1.0 L will be screened with ambulatory oximetry. A log will be used to correlate activity with episodes of desaturation. Patients will be studied with a Holter monitor the same as those in Phase I.

Progress: One patient from group I and three patients from group II have been enrolled. No significant dysrhythmia noted on Holter. Numbers are too small at this time to determine significance.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-77-90 Status: Ongoing  
 Title: The Effect of Early versus Delayed Entry of Coronary Artery Bypass Graft (CABG) Patients into a Cardiac Rehabilitation Program on Selected Measures of Cardiac Function, cholesterol Levels, and Quality of Life.

Start Date 19 Jul 90	Est Comp Date:
Principal Investigator Stacey Adams Dramiga, M.A.	Facility Brooke Army Medical Center
Dept/Svc Cardiac Rehabilitation	Associate Investigators: Antoinette Trafford, MAJ, AN James M. Gilman, LTC, MC Jean Johnson, Ph.D., R.N.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): a) Examine the relationship between time of entry into a cardiac rehab program and measures of physiologic stress, cardiac functioning, cholesterol levels, and quality of life in patients who have had coronary artery bypass graft surgery; b) evaluate the physiological outcomes of CABG patients at six weeks in a cardiac rehab program compared to the same measures after twelve weeks in the program; c) determine the effectiveness of a discharge instruction program of self-regulated activity compared to a comprehensive cardiac rehabilitation program.

Technical Approach: Subjects will be randomly assigned to Group I, entry into the program within 2 weeks after hospital discharge and Group II, entry into the program 6 weeks after hospital discharge. A third group who live too far from BAMC to attend the Cardiac Rehabilitation Program but will be returning to BAMC for follow-up care will be used as a comparative group. All subjects will receive the same instruction on coronary risk factors, exercise and diet prior to discharge and will maintain a daily record of exercise conducted at home. Measures will be obtained on the four variables of interest prior to hospital discharge, after 6 weeks and 12 weeks in a Cardiac Rehabilitation Program (Groups I and II), and at 6 and 12 weeks post-hospital discharge (Group III).

Progress: Entry of subjects into study on hold until status of one of the associate investigators assigned to Operation Desert Shield is determined.



# Detail Summary Sheet

Date: 18 Sep 90      Proj No: C-78-90      Status: Ongoing  
 Title: Can Transesophageal Echocardiographic Screening for Left Atrial Thrombi Preclude Routine Anti-Coagulation of Patients with Atrial Fibrillation before Cardioversion?

Start Date 19 Jul 90	Est Comp Date:
Principal Investigator Joseph P. Johns, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department Medicine/Cardiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): Current medical practice dictates routine anticoagulation of patients with nonvalvular atrial fibrillation existing for three or more days prior to cardioversion. This exposes all patients, including those felt to be at low risk for embolus, to the risks of anticoagulation with coumadin. We hypothesize that the use of transesophageal echocardiography in screening for the presence of atrial thrombi would preclude the need for routine anticoagulation in these patients.

Technical Approach: Patients with atrial fibrillation who are candidates for cardioversion will be randomized to treatment with (standard therapy group) or without Coumadin (experimental group) if the initial transesophageal echocardiogram shows no evidence of intra-cardiac thrombi. After 3 weeks, a repeat transesophageal echocardiogram will be done in order to judge the efficacy of Coumadin in resolving thrombi that may have been observed initially, and to examine the frequency of development of new atrial thrombi while treated or untreated with anticoagulants. After the second transesophageal echocardiogram, all patients without evidence of intra-cardiac thrombi would undergo cardioversion using oral antiarrhythmic agents and/or electrical cardioversion.

Progress: No subjects enrolled. The technical approach is under reconsideration.

# Detail Summary Sheet

Date: 29 Aug 90      Proj No: C-79-90      Status: Ongoing  
 Title: Phase I Evaluation of U73975 Brief Infusion Every 6 weeks in Adult Patients with Solid Tumors

Start Date 19 Jul 90	Est Comp Date:
Principal Investigator Howard Burris, III, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department Medicine/Hem-Oncology	Associate Investigators: Timothy J. O'Rourke, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine the maximum tolerated dose of U-73,975 administered by a brief intravenous infusion every 6 weeks in adult patients with solid tumors. 2) to determine the qualitative and quantitative toxicity and reversibility of toxicity of U-73,975 administered in this fashion. 3) to investigate the clinical pharmacokinetics of U73,975 and to evaluate the rationale for this schedule. 4) to determine the recommended dose and schedule for Phase II therapeutic trials of U-73,975. 5) to collect observations of the antitumor effect of U-73,975 when such events occur.

Technical Approach: Therapy will follow schema outlined in the study protocol.

Progress: Following approval of the protocol, a letter was received from Dr. Daniel D. Von Hoff stating that because of possible pulmonary toxicities, the study has been put on hold until all patients have been followed for six weeks after administration.

# Detail Summary Sheet

Date: 26 Sep 90 Proj No: C-80-90 Status: Ongoing  
 Title: Cytochrome P450, Chemotherapeutic Agents, and Lung Cancer

Start Date 19 Jul 90	Est Comp Date:
Principal Investigator LTC Timothy J. O'Rourke	Facility Brooke Army Medical Center
Dept/Svc Hema/Onc Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To identify individuals with lung cancer who have altered metabolism of cancer chemotherapeutic agents.

Technical Approach: Participants will have DNA isolated from lung tissue and lymphocytes for restriction fragment length polymorphism (RFLP) analysis. RFLP patterns associated with extent of metabolism of specific chemotherapeutic agents will be identified.

Progress: This project is part of a DoD/VA grant that has not yet been funded. Therefore, no patients have been entered.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-90-90 Status: Ongoing  
 Title: Intensive Therapy and Autologous Bone Marrow Transplant with 4-HC  
 Purging in Acute Myelocytic Leukemia (AML) and Acute Lymphocytic Leukemia (ALL)

Start Date 30 Aug 90	Est Comp Date:
Principal Investigator Svetislava J. Vukelja, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Hematology-Onc.	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the effects of autologous transplantation with 4-HC-treated marrow on hematopoietic reconstitution, actuarial relapse rate, and leukemia-free survival in pediatric and adult patients (< 65 y/o) with AML in second or third remission, and ALL in second or third remission.

Technical Approach: Fourteen patients under age 60 will be studied. Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-92-90 Status: Ongoing  
 Title: A Randomized Trial of Heparin in Conjunction with Anistreplase in  
 Acute Myocardial Infarction

Start Date 31 Aug 90	Est Comp Date:
Principal Investigator John F. Seaworth, LTC, USAF MC	Facility Brooke Army Medical Center
Dept/Svc Department Of Medicine/Cardiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To evaluate whether concomitant heparin following dosing with anistreplase reduces the combined incidence of reinfarction, recurrent ischemia, occlusion of the infarct-related coronary artery documented by angiography, or death from cardiac causes before coronary angiography.

Technical Approach: Eligible patients will receive an IV dose of anistreplase. They will then be randomly assigned to receive Heparin or not. Those assigned to the heparin group will receive the heparin by continuous infusion four hours have anistreplase is given. Cardiac catheterization will be done and if the artery is still blocked a balloon angioplasty will be done.

Progress: This is a new study.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-93-90 Status: Ongoing  
 Title: Serum Alpha Transforming Growth Factor Activity in Patients with Squamous Carcinoma of the Head and Neck

Start Date 31 Aug 90	Est Comp Date:
Principal Investigator Don Shaffer, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Hematology-Onc.	Associate Investigators: Howard A. Burris, III, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To determine the levels of serum and urine -TGF prospectively in patients with squamous head and neck cancer.

2) To determine if urine and serum levels of -TGF correlate with disease stage in patients with squamous head and neck cancer.

3) To determine if surgical removal of squamous head and neck cancer will result in a decrease in serum and urine -TGF.

Technical Approach: Blood and urine samples will be obtained and evaluated for -TGF.

Progress: This is a new study.

# Detail Summary Sheet

Date: 2 Oct 90      Proj No: C-95-90      Status: Ongoing  
 Title: Cardiopulmonary Response to Upright Exercise in Patients with Valvular Aortic Stenosis

Start Date 31 Aug 90	Est Comp Date:
Principal Investigator Timothy Martin, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Robert Wozniak, CPT, MC John Seaworth, LTC, USAF MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine the effect of valvular aortic stenosis on cardiopulmonary exercise performance.

2) To determine the relationship between ECHO/Doppler measurements and cardiopulmonary performance in patients with valvular aortic stenosis.

Technical Approach: Following Doppler/echocardiography patients will undergo upright cycle exercise, 20 W/min increments, symptom-limited,, followed by cool-down exercise. During exercise blood pressure, heart rate and heart rhythm will be monitored.

Progress: This is a new study. No reportable data are available.

# Detail Summary Sheet

Date: 24 Oct 90 Proj No: C-99-90 Status: Ongoing  
 Title: Efficacy of Passive Immunization in the Prevention of Infection Due to Klebsiella Pneumoniae and Pseudomonas aeruginosa. (Collaborative study with U.S. Army Medical Research and Development Command)

Start Date 7 Sep 90	Est Comp Date:
Principal Investigator J. William Kelly, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: Craig E. Smith, MAJ, MC James M. Lamiell, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine the effiacy of intravenous immunoglobulin (IVIG) compared with albumin in reducing the incidence of infection caused by Klebsiella and P. aeruginosa bacterial serotypes contained in the two vaccines.

2) To determine whether IVIG delays onset or lesses severity of serotype specific infection.

Technical Approach: Patients entering an ICU or with chemotherapy-induced neutropenia who meet entry criteria will be randomized in a double-blin fashion to receive either hyperimmune IVIG or albumin. Patients will be followed for 6 weeks both clinically and microbiologically for the acquisition of infection and for survival. Serum specimens will e analyzed for levels of binding (ELISA) and phagocytic antibody, and bacteria will be serotyped to determine whether infection occurred with strains included in the vaccines.

Progress: This is a new study.



# Detail Summary Sheet

Date: 25 Oct 90 Proj No: C-104-90 Status: Ongoing  
 Title: Cardiopulmonary Response to Upright Exercise in Cardiac Transplant Patients.

Start Date 10 Oct 90	Est Comp Date:
Principal Investigator Timothy Martin, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Jay Gaucher, CPT, MC Lawrence Pupa, MAJ, MC John Seaworth, LTC, USAF MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine the effect of cardiac transplantation on the hemodynamic and metabolic response to maximal upright exercise in patients with dilated cardiomyopathy.

2) To characterize the hemodynamic and metabolic response to serial maximal upright exercise tests in patients with cardiac transplants.

Technical Approach: Patients with dilated cardiomyopathy under age 65 or patients with heart transplants are eligible for this study. Prior to cardiac catheterization, subjects will undergo bicycle exercise test. Following catheterization and with the catheter still in place a second bicycle exercise test will be performed. Blood pressure, heart rate, pressures inside the leart and lung, oxygen and heart rhythm will be monitored.

Progress: This study was recently approved by the IRB on 10 September 1990.

# Detail Summary Sheet

Date: 25 Oct 90	Proj No: C-107-90	Status: Ongoing
Title: Comparison of Foley Catheter with Standard Replacement Percutaneous Endoscopic Gastrostomy Tube: A Randomized Trial.		

Start Date 10 Oct 90	Est Comp Date:
Principal Investigator Richard T. Shaffer, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Shaielesh C. Kadakia, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To evaluate the longevity and durability of standard replacement gastrostomy tube in patients with previously placed percutaneous endoscopic gastrostomy (PEG).

Technical Approach: Approximately 100 patients will be studied consisting of two groups of 50 patients each, randomly assigned to receive either an all silicone Foley catheter or an all silicone standard commercial replacement kit. All patients who have a PEG will be offered enrollment in the study. All patients who require replacement of deteriorated or malfunctioning PEG tube will be the smaller group. The majority of the patients will have had a PEG placed for at least 4 weeks and have a mature tract between skin and the stomach. The initially placed PEG will be removed and replaced with either a Foley or a standard replacement tube. All patients will be randomized to either a Foley catheter or a standard replacement tube based on a computer generated randomization.

Progress: This study was recently approved by the IRB on 10 September 1990.

# Detail Summary Sheet

Date: 25 Oct 90	Proj No: C-108-90	Status: Ongoing
Title: Phase I-II Trial of Hydroxyurea Using an Oral Intermittent Schedule in Patients with Squamous Carcinoma of the Head and Neck.		

Start Date 24 Oct 90	Est Comp Date:
Principal Investigator Howard M. Burris, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Hem.-Oncology	Associate Investigators: Timothy J. O'Rourke, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine the qualitative and quantitative toxicities of Hydroxyurea given orally in an intermittent scheduled every 3 days in patients with recurrent or metastatic squamous cell carcinoma of the head and neck.

2) To determine the maximum tolerable dose in patients with recurrent or metastatic squamous cel carcinoma of the head and neck using this schedule.

3) To determine the response rate of hydroxyurea in patients with recurrent or metastatic squamous cell carcinoma of the head and neck using this schedule.

4) To characterize the pharmacokinetics/pharmacodynamics of hydroxyurea on this schedule.

Technical Approach: In order to be eligible for this study patients must have a histologically proven squamous cell carcinoma of the head and neck region that has persisted or recurred following definitive surgery and/or radiation therapy, and is not curable by other forms of therapy. Patients with metastatic disease are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: This study was approved by the IRB on 13 August 1990 and by HSC on 19 October 1990.

# Detail Summary Sheet

Date: 30 Oct 90 Proj No: C-80-88 Status: Terminated  
 Title: The Impact of the Use of Active Imagery on Labor and Delivery

Start Date 8 Sep 88	Est Comp Date:
Principal Investigator Cheryl Vaiani, MAJ, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators: Penelope Ward, R.N., Ph.D. Candidate (CDR, USNR)
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine how the use of active imagery affects labor and delivery.

Technical Approach: This two part study will evaluate the psychological progressive of couples through pregnancy and compare the results of the use of active imagery both within group and between experimental and control groups.

Progress: This study was terminated due to failure to submit an annual research progress report.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-14-89 Status: Completed  
 Title: A Study of Selected Demographic and Psychosocial Characteristics as Predictors of Uncomplicated Recovery from Elective Surgery

Start Date 5 Dec 88	Est Comp Date:
Principal Investigator Frances Anderson, MAJ, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators: Mary Edwards, RN, MSN
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 119	
Date of Periodic Review _____	Results _____

Objective(s): To determine the value of selected patient characteristics in identifying those elective surgical patients who, after discharge from the hospital, can be expected to experience recovery with few, if any, problems as opposed to those who experience delays or interruptions in that recovery because of complications related to the surgery.

Technical Approach: One hundred and seventy-seven patients were approached and invited to participate in the study. Subjects were scheduled for one of several elective surgical procedures - cholecystectomy, abdominal hysterectomy, or bowel resection with anastomosis. Prior to surgery, subjects were asked to complete five questionnaires about their health, their family, and themselves. After discharge from the hospital, subjects were contacted three times by phone and asked questions about their recovery.

Progress: Those who completed the data collection numbered 119. Of the remaining 58, 13 did become subjects and returned the initial interview. They were removed from the study for one of the following reasons: requested to be removed (n=2), developed problems that affected their eligibility (n=4), lost contact during follow-up period (n=4), and incomplete data from initial interview (n=2). The other 45 patients who met the criteria for inclusion did not choose to participate.

C-14-89 (Continued)

The sample was predominantly female (n=98), married (n=106), with a mean age of 46. Abdominal hysterectomy was the most frequent surgical procedure (n=63). Cholecystectomies accounted for 47 of the cases with the remaining 7 subjects having bowel resections.

Using discriminant analysis 72% of those experiencing poor recovery were correctly identified. Perceived health was the most consistent variable of significance along with stress in significant contribution to the prediction. Recovery scores for subjects having cholecystectomies were significantly higher than the other two surgeries ( $p<.001$ ). Other findings related to the effectiveness of discharge planning. Ten percent of this sample were unable to decide if their problems were important enough to "bother the doctor". This small percentage was found in the group of subjects who had low total recovery scores. All subjects had had discharge teaching before leaving the hospital, but for some there was limited evidence of their understanding. It has been reported that the anticholinergic effects on the central nervous system as a result of anesthetic drugs could disrupt a patient's recovery. This central anticholinergic syndrome (CAS) may present a transient mental impairment occurring within the first week of surgery, the time during which most discharge teaching occurs.

In light of the information about CAS one is led to speculate that discharge information had been given, but not retained or understood by 10% of the sample. Those subjects needed to be told that their concerns were important enough to warrant a talk with the doctor. Subjects who received the directive to report their problem had various complaints, including fever, cloudy urine, pain and burning on urination, swelling, tenderness and warmth in the calf, wound disruption with pain, tenderness and and drainage, and productive cough with fever.

Conclusions: A simple screening tool for perceived stress and perceived health status has the potential for identifying those patients who are most likely to have problems in the recovery period and who may benefit from additional planning for discharge.

# Detail Summary Sheet

Date: 18 Sep 90 Proj No: C-15-89 Status: Completed  
 Title: Stress and Coping in Childhood Cancer: A Pilot Study.

Start Date 5 Dec 88	Est Comp Date:
Principal Investigator	Facility
Marianne H. Callich, LTC, AN	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Nursing	Dr. Gail Hoevet, University of Texas
Key Words:	Health Science Center, SA
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): 1) To perform the preliminary work on a comprehensive delineation of stresses and positive and negative coping strategies used by parents and their children with cancer and to develop a brief, quantifiable tool to measure stress and coping which will be tested in a second study.

2) To use the information obtained to analyze the effectiveness of coping strategies and plan intervention studies aimed at maximizing the positive coping strategies thereby improving the quality of life for both children and their families during this major event.

Technical Approach: Subjects will be identified in children's cancer clinics at Brooke Army Medical Center, Wilford Hall, and Santa Rosa Medical Center. The children for this study will be male or female, between the ages of 6 and 14 with a diagnosis of leukemia, lymphomas, and malignant tumors in either the diagnosis, treatment or completion of treatment stage of illness. Appointments will be made for a home visit to separately interview the parents and the child with appropriate interview schedule. A follow-up appointment will be conducted at one week to complete the interview. A teacher who has had contact with the child for at least one term will be identified by the child and family and asked questions in relation to stress and coping strategies used by the child.

Progress: Thirty children with cancer and their parents were interviewed. Data were analyzed using classic content analysis procedures. Ten categories of coping for children and twelve for parents were identified. Based upon the information derived from this analysis Likert type scales were developed to measure coping behavior of parent and child. Stress inventories were developed for parent and child. These instruments will be used in phase II of the program of research.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-34-89 Status: Terminated  
 Title: Perceived Role Competency Differences Between Emergency, Intensive Care, and Medical/Surgical Army Nurse Corps Officers

Start Date 21 Feb 89	Est Comp Date:
Principal Investigator Michael A. Calder, MAJ, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine whether differences exist in how emergency, intensive care, and medical-surgical Army nurses perceive actual, ideal, and preparedness competencies of assessment and triage.

Technical Approach: This is a descriptive comparative survey of perceived role competency differences, in a convenience sample of 366 Army Nurse Corps officers. Anonymously completed emergency nurse competencies questionnaires will be analyzed using one-way ANOVA, Scheffe's post hoc comparison, and multiple regression statistical methods.

Progress: Terminated due to failure of principal investigator to submit report of data analysis.



# Detail Summary Sheet

Date: 15 May 90	Proj No: C-59-89	Status: Terminated
Title: The Efficacy of an Early Cardiac Rehabilitation Program as Measured by Maximum Aerobic Capacity During Metabolic Exercise Stress Test, Left Ventricular Ejection Fraction as Measured by MUGA, Change in Lipid Profile, and Perceived Quality of Life		
Start Date: 4 Apr 89	Est Comp Date:	
Principal Investigator (vice Anderson)	Facility	
Antoinette Trafford, MAJ, AN	Brooke Army Medical Center	
Dept/Svc	Associate Investigators:	
Department of Nursing	Stacey Adams Dramiga, M.A.	
Key Words:	James Gilman, MAJ, MC	
Accumulative MEDCASE	Est Accumulative	
Cost:	OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 2		
Total Number of Subjects Enrolled to Date: 2		
Date of Periodic Review 14 May 90	Results Terminate	

Objective(s): To determine if those patients who have undergone coronary artery bypass grafting entering a cardiac rehabilitation program within two weeks post surgery will have significant changes in the following clinical parameters: maximum aerobic capacity, exercise tolerance, left ventricular ejection fraction, lipid profile, and perceived quality of life.

Technical Approach: Patients will be randomized into either the control or experimental group using a random table of numbers. Both groups will undergo measurement of the following parameters: perceived quality of life, ejection fraction by MUGA, exercise tolerance as determined by treadmill, and lipid profile preoperatively, prior to discharge, and 3 months post discharge from the hospital. Those randomized to the experimental group will enter a cardiac rehabilitation program one week post discharge. They will be asked to keep a daily log of various activities to include walking, biking, arm work, stair climbing, warmups and warmdowns. The control group will not enter any form of organized cardiac rehabilitation program but will receive instructions regarding risk factor modifications and life style change.

Progress: After studying two patients, it was determined that there were defects in the study design. Therefore, the protocol was terminated, and a new protocol will be submitted.

# Detail Summary Sheet

Date: 1 Aug 90 Proj No: C-88-89 Status: Completed  
 Title: Evaluation of a Stress Assessment Scale as a Measurement of Stress

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Beverly J. Dreyer, CPT, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review n/a	Results

Objective(s): To assess the reliability and validity of the stress related items of the Fit to Win Health Risk Assessment as a measure of stress. The 13 stress related items comprise the Stress Assessment Scale (SAS).

Technical Approach: The target population was active duty Army personnel. Three groups were used in the study and were designated as normal, low stress, and high stress. The sample for the normal group (N=174) were officers attending the Army Medical Department Officers Advanced Course (AOAC) (N=52), enlisted soldiers attending the Basic Noncommissioned Officers Course (BNOC) (N=54), and soldiers attending the General Medical Orientation (GMO) (N=68). The sample for the high stress group (N=26) were outpatients from the Psychiatric Day Facility, Brooke Army Medical Center. The low stress group were randomly selected subjects from the normal group with four or less positive answers on the General Health Questionnaire-30.

Progress: There was a significant difference between the mean scores of the total SAS in the high stress and low stress groups ( $t=5.23$ ,  $df=49$ ,  $p < 0.000$ , 2-tailed). Overall, the findings suggested that the SAS has high reliability and validity as a screening measurement of stress for soldiers in the AOAC, BNOC, and GMO course. The subscales have low to moderate reliability and validity as measurements of components of stress, although there is some question as to the reliability of the activatores subscale in the GMO population.

# Detail Summary Sheet

Date: 8 Aug 90 Proj No: C-89-89 Status: Terminated  
 Title: Differences in Mixed Venous Oxygen Saturaton Related to Continuous vs. Intermittent Suctioning

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Barbara A. Goodwin, MAJ, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To compare the differences in mixed venous oxygen saturation (SvO<sub>2</sub>) produced immediately after continuous and intermittent endotracheal suctioning.

Technical Approach: All patients shceduled for cardiac surgery who meet the inclusion criteria will be asked to participate. Pre and post-suctioning hyperoxygenation will be administered using the ventilator. If positive end expiratory pressure (PEEP) is in use, the PEEP will be maintained throughout the sucitoning procedure. At this point the first SvO<sub>2</sub> will be taken. The subject will the receive the suction treatment. Immediately after the suction pass is completed a second SvO<sub>2</sub> will be taken. There will be a minimum of 30 minutes between suctioning trials to allow the SvO<sub>2</sub> to stabilize before the initiation of a second trial.

Progress: Study terminated due to PCS of principal investigator.

# Detail Summary Sheet

Date: 9 Aug 90 Proj No: C-90-89 Status: Terminated  
 Title: Comparison of Two Methods of Re-Warming Patients in the Post Anesthesia Care Unit

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Laura Terriquiz-Kasey, CPT, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators: Toni Malpass, RN Karena Tarrenet, RN
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review: _____	Results: _____

Objective(s): To evaluate the most effective manner of re-warming patients in a postoperative setting.

Technical Approach: Each patient needing re-warming per temperature on admission to PACU and meeting the eligibility criteria for entry will be included. Each patient will be assigned a heat lamp or Bair Hugger blanket. The patient's temperature will be recorded q15 minutes. It will be taken by PACU nursing staff with a IVAC 4000. Temperatures will be taken orally or axillary depending on patient cooperation and alertness. Temperature measurements will be repeated until the temperature is adequate for discharge criteria.

Progress: Study terminated due to PCS of principal investigator.

# Detail Summary Sheet

Date: 18 Sep 90 Proj No: C-2-90 Status: Completed  
 Title: Development of Self-Concept Over the Trimesters of Pregnancy

Start Date 14 Nov 90	Est Comp Date:
Principal Investigator Sharon L. Hall, R.N.	Facility Brooke Army Medical Center
Dept/Svc Ph. D. Candidate, Univ. of Texas Austin	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine self concept changes over the three trimesters of pregnancy in primigravidas.

Technical Approach: A descriptive-exploratory study of longitudinal design with a final sample of 32 was completed. Each participant was asked to complete the Tennessee Self-Concept Scale and the Lederman Prenatal Self-Evaluation Questionnaire II three times toward the end of each trimester. Semi-structured interviews with twelve volunteers were conducted late in the third trimester, upon completion of all data collection points. Data was analyzed through MANOVAs (instruments) and inductive analysis (interviews).

Progress: Findings indicate that there was statistically significant change in several subscales of both instruments. One subscale of the Tennessee Self-Concept Scale, Social Self changed significantly ( $P < .05$ ) over the three trimesters of pregnancy. Quantitative analysis of the Lederman Self-Evaluation Questionnaire also indicated change ( $p < .05$ ) in four subscales: acceptance of pregnancy, identification of the motherhood role, fear of pain and loss of control, and preparation for labor. Data obtained from the twelve interviews supported changes noted in the instruments. However, there was no change in general self-concept over the three trimesters of pregnancy.

C-2-90 (continued)

Most of the women interviewed indicated that pregnancy was an exciting and fearful time, adding new dimensions to their lives, but that pregnancy did not really change how they thought about themselves. This information should serve to emphasize the intervention of treating each individual as an individual and meet the unique needs of each pregnant client. Pregnancy may not be as psychologically disruptive as previously thought. This information would help professionals better organize and time information to be given to the expectant couple in anticipation of the potential problem areas that are to follow.

# Detail Summary Sheet

Date: 30 June 1990 Proj No: C-15-90 Status: Completed  
 Title: Gender Differences in Clinical Work Preferences, Desire for Transfer, and Perceived Stress Among Military Staff Nurses.

Start Date 17 Jan. 90	Est Comp Date:
Principal Investigator	Facility
Steven E. Leary, MAJ	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
UTHSCSA	
Key Words:	
Stress	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): The purpose of this study is to determine if differences exist between male and female nurses in perceived role conflict, role ambiguity, frequency and intensity of stressful events, and clinical work preferences. The study will also determine if the practice of assigning individuals to work areas where they may not be prepared or do not want to work has any effect on these individuals in terms of experienced role conflict, role ambiguity, frequency and intensity of stressful events, and clinical work preferences.

Technical Approach: The study sample consisted of 213 active-duty military nurse officers. The sample was drawn from two Air Force medical centers and one Army medical center. Of the total 162 were female and 51 were male. Overall, the males in this sample were significantly older, more likely to hold a degree from a discipline outside of nursing and more likely to be married than were the females.

The following hypotheses were examined. 1) There should be a positive correlation between role conflict, role ambiguity, and stress. 2) Individuals assigned to work in clinical areas where they did not desire to work would feel greater role conflict than those who were working in areas they did desire. 3) Males should suffer more role conflict, role ambiguity and stress than females in the traditional hospital nursing role. 4) Nursing career aspirations of male nurses would be significantly different from those of female nurses.

Progress: Hypothesis one was supported. Both mean role conflict and mean role ambiguity scores correlated significantly and positively with stress at .4987 for role conflict and stress and .4311 for role ambiguity and stress ( $p = .002$ , two-tailed).

C-15-90 (continued)

Hypothesis two was supported. Individuals who did not desire to work in the clinical area where they were assigned, or who had no interest in the area, and did not enjoy their clinical work assignment suffered more role conflict ( $\underline{r} = .2645$ ,  $p = .002$ , two-tailed), more role ambiguity ( $\underline{r} = .1994$ ,  $p = .02$ , two-tailed), and more stress ( $\underline{r} = .1711$ ,  $p = .02$ , two-tailed) than those who did not feel this way about their clinical assignment.

Hypothesis three was not supported. Male nurses did not suffer more role conflict, role ambiguity, and stress than female nurses. In fact, the males reported slightly less role conflict and stress than did females while mean scores for role ambiguity were almost identical between genders. None of these differences were significant.

Hypothesis four was supported. The rank ordering of career goals was different for female versus male nurses. Overall, males demonstrated more interest in administrative roles and anesthesia as compared to other nursing roles than did the females. Females, on the other hand, were more interested in maternal-child nursing roles and clinical nurse specialist roles than were the males.



# Detail Summary Sheet

Date: 25 Oct 90 Proj No: C-103-90 Status: Ongoing  
 Title: Childhood Cancer: Coping of Child and Parent and Correlates.  
 (Collaborative Study with University of Texas Health Science Center)

Start Date 10 Oct 90	Est Comp Date:
Principal Investigator Gail Hoevet, Ph.D.	Facility Brooke Army Medical Center
Dept/Svc University of Texas Health Science Ctr	Associate Investigators: Jean Johnson, Ph.D.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To refine stress coping instruments for children with cancer and for their parents that were developed during the first phase of this program.

Technical Approach: Subjects will be identified in Children's Cancer Clinics at BAMC and Santa Rosa Medical Center. The children will be male or female between the ages of 6 and 14 with a diagnosis of leukemia, lymphoma or malignant tumor in either the diagnosis, treatment or completion of treatment stage of the illness. Parents of these children will comprise the parent sample. Completion of the stress and coping, self concept and temperament questionnaires may take place in the subjects homes or in the clinic, whichever is most convenient.

Progress: This is a new study approved by the IRB 10 September 1990.

### Detail Summary Sheet

Date: 14 Aug 90      Proj No: C-85-88      Status: Completed  
 Title: Hormonal and Sonographic Assessments of First Trimester Pregnancies  
 Complicated by Vaginal Bleeding

Start Date    8 Sep 88	Est Comp Date:
Principal Investigator (vice Valento) Kenneth Higby, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators: Clifford C. Hayslip, LTC, MC
Key Words: Beta HCG levels	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review    8 Sep 90      Results    Completed	

Objective(s): To determine the value of serum progesterone, estradiol, and beta HCG levels in the assessment of complicated first trimester pregnancies, and to compare vaginal and abdominal ultrasound in the early diagnosis of abnormal pregnancies.

Technical Approach: Approximately 200 patients presenting to the GYN Clinic with vaginal bleeding and known or suspected pregnancy will be asked to participate in the study. Each patient will have serum beta HCG, progesteron and estradiol levels drawn. The evaluating physician will perform a pelvic exam and both a vaginal and abdominal ultrasound. If an intrauterine pregnancy is confirmed by ultrasound, repeat hormonal levels and ultrasound will be repeated in 2-7 days. Patients with suspected ectopic pregnancy will also have an initial hormonal evaluation and ultrasounds performed. Those patients not undergoing immediate surgery will have repeat hormonal levels and ultrasound performed in 24-48 hours. Patients with threatened miscarriage will be followed in the same manner as described for ectopic pregnancies.

Progress: Study confirmed hypothesis that serum progesterone and serum estradiol levels can be used to help diagnose abnormal pregnancies. We also demonstrated the importance of transvaginal sonogram in evaluating patients presenting with bleeding/pain in the first trimester. Serum progesterone seems to be as sensitive as serum estradiol.

# Detail Summary Sheet

Date: 29 Nov 90 Proj No: C-43-89 Status: Ongoing  
 Title: Inter-Observer Variation in the Classification of Endometriosis

Start Date 28 Feb 89	Est Comp Date:
Principal Investigator Clifford C. Hayslip, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Endometriosis	
Accumulative MEDCASE Cost: \$15,104.00 (AFSGO)	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 50	
Total Number of Subjects Enrolled to Date: 50	
Date of Periodic Review	Results

Objective(s): To determine the reproducibility of the American Fertility Society classification scores in assessing the severity of endometriosis found at the time of diagnostic laparoscopy by different observers.

Technical Approach: Twenty women undergoing diagnostic laparoscopy for infertility and endometriosis will be studied. A VHS video camera will be used to systematically record the pelvic findings at the time of laparoscopy. The pelvic findings will be evaluated at laparoscopy: (1) anterior peritoneum, (2) right round ligament, (3) right broad ligament, (4) right tube, (5) right ovary, (6) uterus, (7) left round ligament, (8) left tube, (9) left ovary, (10) cul-de-sac and uterosacral ligaments. The pelvic findings on each patient will be recorded and saved on standard VHS cassettes. The video cassettes of the 20 patients will be reviewed by three groups of physicians. Each member will be asked to score each patient on the basis of the AFS revised classification for endometriosis.

Progress: Approximately 50 women have undergone diagnostic laparoscopy in the study and 22 were found to have endometriosis. Ten of the patients with different degrees of endometriosis are having their pelvic findings recorded on one VHS tape which will be circulated to the participating physicians. The physicians will score the severity of endometriosis according to the revised AFS classification. After the score sheets are returned, the results will be tabulated.

# Detail Summary Sheet

Date: 6 Mar 90 Proj No: C-102-89 Status: Terminated  
 Title: The Effect of Human Surfactant Treatment of Hyaline Membrane Disease on the Incidence of Pneumothorax. (Collaborative Study with Keesler USAF Hospital)

Start Date: 1 Aug 89	Est Comp Date:
Principal Investigator Arthur S. Maslow, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics and Gynecology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the incidence of pneumothorax in infants with HMD who receive replacement surfactant, as compared with historical controls.

Technical Approach: Amniotic fluid will be collected at the time of delivery by cesarean section. The fluid will be sent to Keesler USAF Medical Center where surfactant will be removed from the amniotic fluid and processed in their laboratory. The final surfactant product is used to treat infants with hyaline membrane disease.

Progress: The study was terminated due to the availability of two alternative surfactants which are sterile and effective.

# Detail Summary Sheet

Date: 29 Nov 90      Proj No: C-124-89      Status: Ongoing  
 Title: To Compare the Effects of Continuous Versus Cyclic Continuous Estrogen-Progestin Therapy on Fasting Serum Lipoproteins in Postmenopausal Women

Start Date: 31 Oct 89	Est Comp Date:
Principal Investigator (vice Raez) Clifford C. Hayslip, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 28	
Total Number of Subjects Enrolled to Date: 28	
Date of Periodic Review	Results

Objective(s): To compare the effects of continuous versus cyclic hormonal replacement therapy on the fasting serum lipoprotein profiles (FLP) of postmenopausal women.

Technical Approach: One hundred postmenopausal patients routinely seen at the GYN clinic will be asked to participate in the study. Women who have been on cyclic ERT, women taking Premarin only, and women on no hormonal replacement will be the three study groups. Patients on cyclic ERT, will have baseline FLP drawn on days 1, 15 and 25 of the month. At this time these patients will be switched to continuous therapy, and their FLP rechecked after two months in continuous therapy. Patients on Premarin alone, and postmenopausal patients on no therapy will be asked to have a single baseline FLP performed prior to entering the study. At this time they will be placed on three months of cyclic therapy, followed by three months of continuous therapy. FLP will be performed on these patients in a similar manner on days 1, 15 and 25 of the third month of cyclic therapy, and at random a single time after two months of continuous therapy.

Progress: To date, 28 women have participated in the study, and a statistical analysis of the preliminary data is being performed. Dr. Raez has finished his residency and is now stationed at Fort Ord. Dr. Hayslip will take over as PI for the present.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-36-90 Status: Completed  
 Title: Fetal Shoulder Area Measurement: A Predictor of Shoulder Dystocia or Other Abnormalities of Vaginal Delivery?

Start Date 7 Mar 90	Est Comp Date:
Principal Investigator Arthur S. Maslow, LTC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators: Ann Marie Morgan, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 189	
Date of Periodic Review _____	Results _____

Objective(s): At the present time there is/are no reliable predictor(s) of shoulder dystocia (entrapment of the anterior shoulder behind the maternal pubic symphysis after delivery of the fetal head) during vaginal delivery. We have developed a reproducible ultrasound measuerment of the fetal shoulder area. Our objective is to longitudinally measure fetal shoulder area, along with other already established fetal measurements, on most patients registering for obstetric care at Brooke Army Medical Center. Simply stated, we wish to know if a critical shoulder area measurement (SAM) can be determined, above which accurately predicts shoulder dystocia or other abnormalities of vaginal delivery, i.e. failure to descend.

Technical Approach: All patients enrolled in the clinic for obstetrical care are given a first trimester ultrasound examination. The patients are then studied at 3-4 week intervals beginning at 16 weeks of gestation until 36 weeks gestation when they will be studied weekly until delivery. The following measurements are obtained: biparietal diameter, mean head diameter, mean abdominal diameter, femur length, shoulder area measurement, and maternal weight. The entire examination is performed on an ADR 3000 ultrasound with a 3.5 MHz transducer at 25% power. Preliminary studies have demonstrated an intra- and inter-observer mean difference for the shoulder area measurement of 0.8 mm +/- 1.0 mm, respectively.

Progress: Patients excluded from analysis included four patients who developed pre-eclampsia, 6 with class A diabetes mellitis, 7 whose husbands were transferred to other duty locations, and 80 patients who had 3 or 13ss ultrasound examinations over the course of the study. The remaining 92 patients accounted for 612 studies. Mean  $\pm$  1 SD vs. gestational age is demonstrated in figure 1. Table

C-36-90 (continued)

of Mean  $\pm$  2 SD was prepared (Table 1). "Best-fit" line prepared, defined by straight line with  $R^2 = .9848$  (Fig. 2).

Conclusion: SAM is an easily obtained reproducible measurement with high correlation to gestational age. Normative data was established. Other studies will follow.

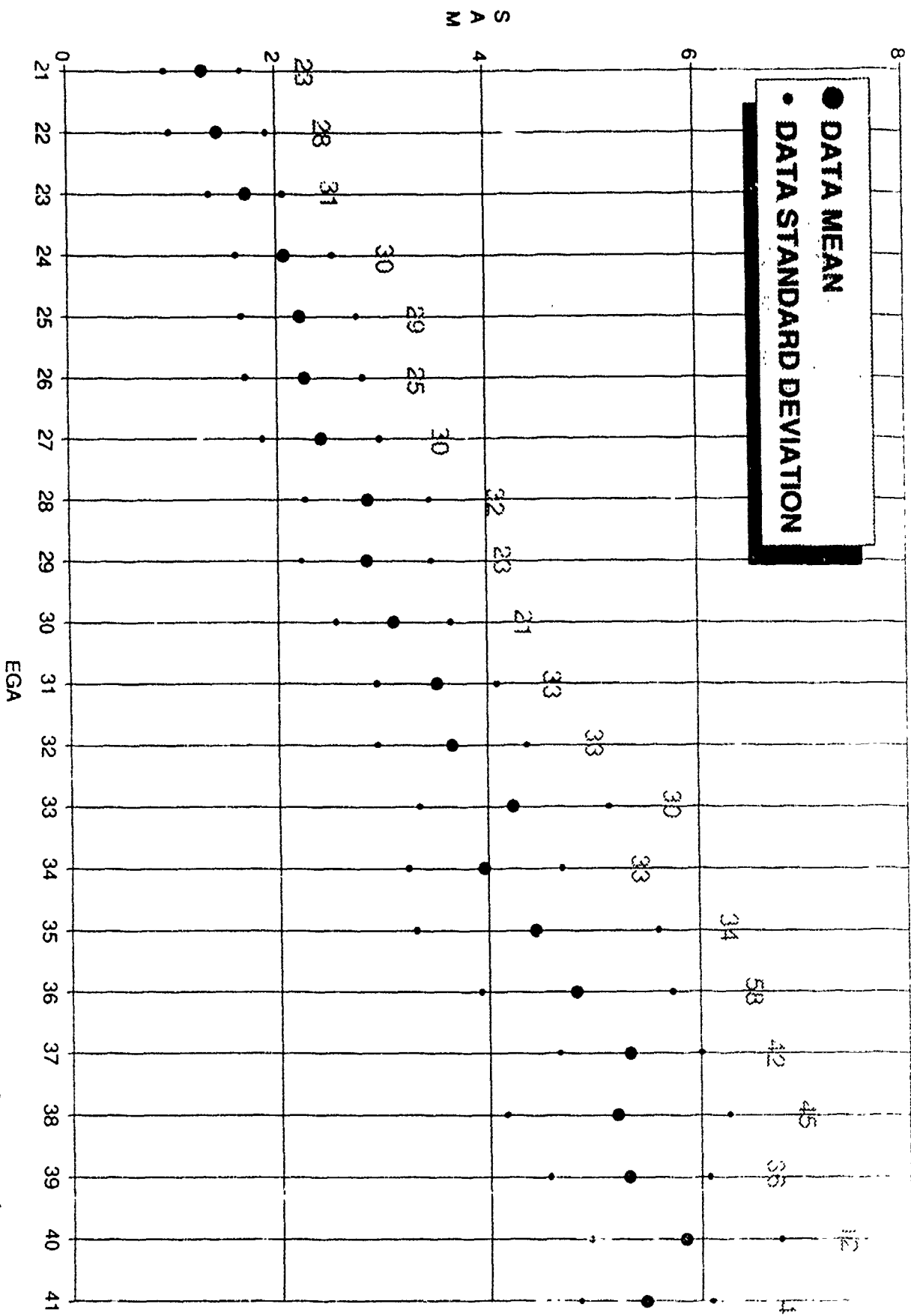


FIG I - number above data mean SD is "n" patients/week of gestation



▲ Data Points  
— Fitted Line

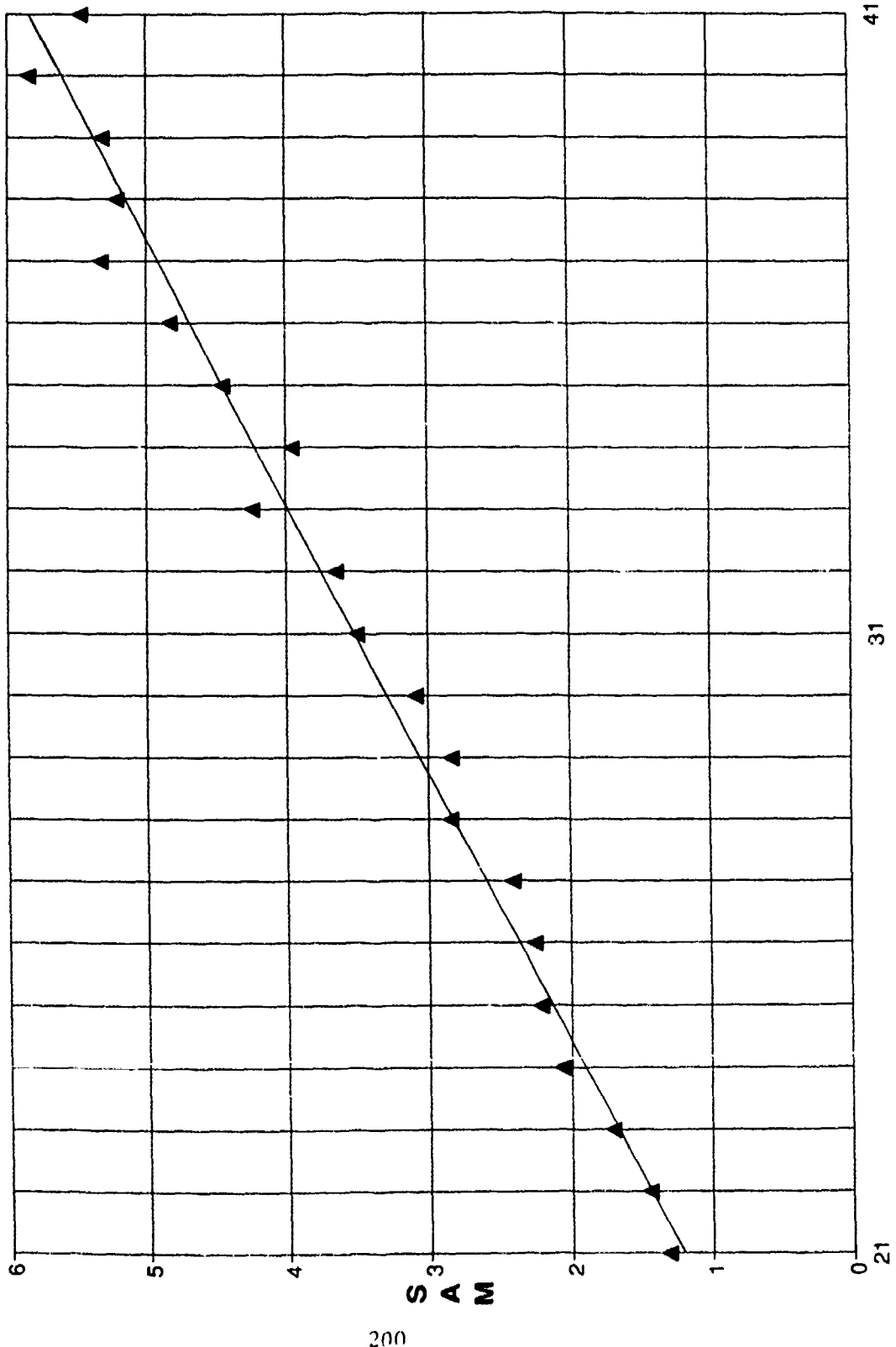
SAM Fit:

R-Square:  
.9828

Root MSE:  
.1950041

C (1):  
.23185766

C (0):  
-3.66263



EGA

FIG II

Table I

WEEKS	GESTATION	NO. OF MEASUREMENTS	ARITHMETIC MEAN (cm <sup>2</sup> )	MASLOW
				+/-2SD (cm <sup>2</sup> )
21		23	1.3	.72
22		28	1.5	.92
23		31	1.7	.70
24		30	2.1	.90
25		29	2.2	1.08
26		25	2.3	1.12
27		30	2.4	1.12
28		32	2.9	1.20
29		23	2.8	1.24
30		21	3.1	1.12
31		33	3.5	1.16
32		33	3.7	1.44
33		30	4.2	1.82
34		33	4.0	1.48
35		34	4.5	2.40
36		58	4.8	1.82
37		42	5.3	1.34
38		45	5.2	2.20
39		36	5.3	1.50
40		12	5.8	1.80

FETAL SHOULDER AREA

# Detail Summary Sheet

Date: 14 Sep 90      Proj No: C-49-90      Status: Ongoing  
 Title: Fetal Breathing Movements, Prostaglandins, and Byproducts of Infection in Preterm Labor.

Start Date 27 Mar 90	Est Comp Date:
Principal Investigator Randall Davis, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Perinatology Service	Associate Investigators: Arthur S. Maslow, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review n/a	Results

Objective(s): 1) To establish or refute the proposal that the absence (or diminution) of fetal breathing motion during preterm labor is correlated with the local production of prostaglandins and/or their metabolites by the decidua (endometrium in contact with fetal membranes) or the fetal membranes; and 2) to determine if a decrease in fetal breathing motion correlates with the presence of bacterial cell wall products (lipopolysaccharide), and/or membrane markers of infection (IL-1B; Tumor Necrosis Factor) that are detectable in amniotic fluid.

Technical Approach: The study group will consist of pregnant females at 20-36 weeks of gestation in established preterm labor who have not yet been given tocolytic therapy. These patients will be treated according to standard institutional protocol for preterm labor. This includes blood and urine tests, an IV, ultrasound, amniocentesis, and medicines to stop labor. An additional serum sample will be obtained for PGFM will be drawn 6 hours after initial therapy. If there is evidence of intra-amniotic infection, or of fetal lung maturity, tocolysis will be stopped. Further serum samples will be drawn for PGFM at the times electrolytes are tested. Aliquots of amniotic fluid and maternal serum will be frozen within 8 hours of collection. At the end of the study period the specimens will be thawed and analyzed in batch runs. Comparisons of outcome, presence or absence of fetal breathing movements, and presence of PGE2, PGF2x, PGFM, LPS, IL13 will be made.

Progress: One patient who met criteria was enrolled. Outcomes of her pregnancy and prostaglandin studies are pending.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-64-90 Status: Ongoing  
 Title: The Effects of Magnesium Sulfate Tocolysis on Electrolytes and Hormones of Calcium Hemostasis

Start Date 9 May 90	Est Comp Date:
Principal Investigator	Facility
Ralph E. Joseph, CPT, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Obstetrics-Gynecology	Arthur S. Maslow, LTC, MC
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 8	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review	Results

Objective(s): 1) Establish in detail the extent of electrolyte and hormonal alterations caused by therapy with Magnesium Sulfate for the preterm labor versus the pre-eclamptic patient and their neonates. 2) Determine if such electrolyte and hormonal disturbances correlate with the type of intravenous fluids infused or concentration of Magnesium Sulfate given. 3) Demonstrate that despite probable statistically significant changes in some electrolytes and hormones, clinically significant events are extremely rare, in support of available anecdotal literature.

Technical Approach: This study will include 25-30 patients in preterm labor treated in the standard manner with magnesium sulfate. Urinary electrolytes, serum/urine osmolarity, PTH, calcitonin, and anion gap will be evaluated. The control group will include 5-10 pre-eclamptic patients as positive controls and 5-10 normal patients as negative controls.

Progress: Eight patients have been enrolled in the study - three with pre-eclampsia, two controls, and three pre-term labor.

# Detail Summary Sheet

Date: 9 Oct 90 Proj No: C-65-86 Status: Terminated  
 Title: Identifying Pathogenic Coryneform Bacteria

Start Date 8 Jul 86	Est Comp Date:
Principal Investigator S. Vern Juchau, COL, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology/Microbiology	Associate Investigators: Robert G. Whiddon, Jr., LTC, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 883.28
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To investigate a means of identifying and separating coryneform bacteria that can be isolated from the human body.

2) To attempt to correlate identified groups with normal flora or pathogenic potential.

3) To provide clinical microbiologists and physicians with a tool to better interpret the significance of the isolation of a gram-positive, non-spore forming bacillus which does not fall into one of the groups of known primary pathogens.

Technical Approach: The major focus of this study will be to classify coryneform bacteria of human origin on the basis of cellular fatty acids with the aid of a gas-liquid chromatography. Profiles of ATCC strains of human coryneforms will be constructed to serve as a data base to which clinical isolates will be compared.

Progress: The principal investigator on this study has retired. Since no other department members were interested in continuing his work, the study was terminated.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-64-88 Status: Ongoing  
 Title: Rapid Laboratory Detection of Mycoplasmosis Using a Radiometric Device

Start Date 14 Jul 88	Est Comp Date:
Principal Investigator William Nauschuetz, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To determine if Mycoplasma pneumoniae can be detected from clinical specimens using a system by which the pathogen is selected and detected by the evolution of <sup>14</sup>C-labelled CO<sub>2</sub> from medium containing <sup>14</sup>C-labelled glucose.

2) To determine if the amount of liberated <sup>14</sup>C-labelled CO<sub>2</sub> allows sufficient sensitivity such that growth of the M. pneumoniae is detected significantly faster than allowed by conventional isolation techniques.

3) To mold this detection system into one which is compatible with the BACTEC Blood Culture Instrument, which is a common microbiology laboratory tool, found in a significant percentage of clinical laboratories.

Technical Approach: To develop a system by which SP4 medium will be made to include <sup>14</sup>C-labelled glucose, as well as ampicillin, fungizone, crystal violet and thallium acetate to inhibit other bacterial, mycotic, and mycoplasmal species found in respiratory systems.

Progress: Data from the study have been compiled, and the system was submitted to JAG, DA for patent evaluation. The packet has passed the legal studies and will be sent to the Patent Office for assignment of a Patent Pending number. Manuscript is being finalized.

# Detail Summary Sheet

Date: 22 Aug 90 Proj No: C-67-89 Status: Completed  
 Title: A Comparison of Enzyme-Linked Immunoassay and Papanicolaou Stain versus Cell Culture for Detecting Chlamydial Trachomatis Cervical Infections

Start Date: 5 May 89	Est Comp Date:
Principal Investigator Bradley N. Harper, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology	Associate Investigators: S. Vern Juchau, COL, MS Margit Gerardi, CPT AN Phillip L. Day, LTC, MC Helen Viscount, 1LT, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 580	
Total Number of Subjects Enrolled to Date: 580	
Date of Periodic Review 11 May 90	Results Completed

Objective(s): 1) To compare the Chlamydiazyme test versus cell culture in the diagnosis of Chlamydia trachomatis infections in young asymptomatic females.

2) To determine the positive predictive value of intracellular inclusions for Chlamydia trachomatis infections.

Technical Approach: A prospective study was performed comparing an Enzyme Immunoassay (EIA) antigen detection test (Chlamydiazyme) to cell culture on 580 female active duty soldiers. As an adjunct study, Papanicolaou stains of cervical smears from these same patients were evaluated for the presence of cytoplasmic inclusions suggestive of Chlamydial infection.

Progress: Eighteen of the 580 patients had a positive cell culture (3.1%) with 17 positive by EIA (94% concordance). An additional 38 patients were positive by EIA with a negative culture (total of 55 positive EIA tests for 9.5% prevalence). Twenty-nine of these 38 patients with a positive EIA and negative culture had either historical, clinical, or laboratory evidence to suggest an infectious process. Two of the nine patients that were positive by EIA and negative by culture were negative by both methodologies upon retesting without treatment. None of 453 Pap smears deemed adequate showed intracytoplasmic inclusions, 42 of which had either a positive culture, EIA, or both.

This study shows Pap stains to be insensitive to the presence of Chlamydial infection. Comparing EIA to culture is difficult given the poor sensitivity of culture. Possible confounding factors include the requirement for viable

C-67-89 (Continued)

organisms to produce a positive culture, an adequate inoculum to produce cytoplasmic inclusion vacuoles, nonspecific binding of the EIA marker immunoglobulin to mucus, and false positive binding to rectal flora. Analysis of the patient data favors the interpretation of Chlamydiazyme is more sensitive than culture to the presence of the organism and performs well as a screening test. The possible higher sensitivity of EIA can create apparent false positive results.



# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-35-90 Status: Ongoing  
 Title: Have HIV-Positive Patients from BAMC Been Co-Infected with the Newly Described Mycoplasma incognitus?

Start Date 6 Feb 90	Est Comp Date:
Principal Investigator William F. Nauscheutz, CPT	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine if the newly described Mycoplasma incognitus appears in the stored sera of known EIA HIV-positive patients.

Technical Approach: This study will determine if the organism Mycoplasma incognitus can be recovered from the sera of known HIV-positive patients. 1 mL aliquots of HIV-positive sera will be removed and microfuged at a rate sufficient to pellet mycoplasmal cells. The pellet will be resuspended and inoculated into Mycoplasma bottles which are completely closed systems containing SP4 medium, radioactively labelled glucose, and antibiotics which help select against non-mycoplasmal bacteria. The bottles will be read daily on the Bactec 460 Blood Culture Device to detect the evolution of radioactive CO<sub>2</sub>. If the gas evolves while the medium remains clear, the organism will be transported to the P3 facility at the UTHSC for complete identification.

Progress: Screening methods for the presence of a virulent strain of Mycoplasma fermentans (formerly referred to as M. incognitus) is being performed in blood of HIV-positive patients. The blood specimens being used are those which have already been clinically tested by Flow Cytometry. The screening method is polymerase chain reaction (gene amplification). This testing is performed by Dr. Victor Tryon, Department of Microbiology, UTHSCSA. Approximately 45 specimens have been submitted for testing. The organism has not been found in any of the specimens to date. In our laboratory, ELISA screening is performed for anti-Mycoplasma fermentans in the sera of HIV-positive patients. The antigen (M. fermentans) has been harvested, and the other ELISA reagents (goat anti-human conjugate, both IgM and IgG) will be ordered in the near future.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-45-90 Status: Ongoing  
 Title: Incidence of Adenocarcinoma of the Prostate at Autopsy: Importance of Step Sectioning Technique.

Start Date 27 Mar 90	Est Comp Date:
Principal Investigator Brad Harper, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review	Results

Objective(s): To determine the autopsy prevalence of adenocarcinoma of the prostate using a meticulous step sectioning technique.

Technical Approach: This study proposes to use meticulous step-sectioning techniques to determine a more accurate prevalence of occult carcinoma of the prostate in nodules discovered during the course of autopsy.

Progress: Due to extensive sectioning required and unanticipated staff shortages, little progress has been made.

# Detail Summary Sheet

Date: 20 Aug 90 Proj No: C-34-85 Status: Ongoing  
 Title: Effect of Dietary Modifications on Weight Change in Obese Children with Different Insulin Responses to Glucose and Leucine Challenge.

Start Date 29 Apr 85	Est Comp Date:
Principal Investigator Chandra M. Tiwary, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Juliann M. Walker, LT, MS
Key Words: Children, obese	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 10	
Total Number of Subjects Enrolled to Date: 108	
Date of Periodic Review 14 May 90	Results Continue

Objective(s): 1) To determine if specific dietary modifications can result in improved weight reduction in certain categories of obese children.

2) To develop a profile for these children by identifying common characteristics according to their insulin responses to tolerance testing.

Technical Approach: Eligible patients will have a complete history, physical, CBC, SMAC-20, oral glucose tolerance test (1.75 gm/kg, max. 100 gms); and oral leucine tolerance test (150 mg/kg). Subjects will be classified into elevated and normal insulin groups in accordance with their insulin response to glucose and leucine challenges. All participants will receive dietary instructions and will be provided with behavior modification instructions.

Progress: With the inclusion of LT Walker, staff dietitian, the dietary portion of this study should be completed within the next year.

# Detail Summary Sheet

Date: 8 Aug 90 Proj No: C-21-86 Status: Terminated  
 Title: A Comparison of High Frequency Oscillatory Ventilation and Conventional Ventillation in the Management of Respiratory Distress Syndrome in Infants Less Than 1750 Grams. (Collaborative Study with Wilford Hall USAF Hospital)

Start Date 19 Mar 86	Est Comp Date:
Principal Investigator Howard Heiman, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Jan Carter, MAJ, MC John Woodall, COL, MC
Key Words: Syndrome, respiratory distress	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 470.00
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 12	
Date of Periodic Review 12 Mar 90	Results Continue

Objective(s): To evaluate the efficacy of using high frequency oscillatory ventilation (HFOV) in the management of respiratory distress syndrome (RDS) in premature infants, as compared to using the conventional neonatal ventilation (CV) therapy of intermittent mandatory ventilation and continuous distending pressure.

Technical Approach: The study population will consist of premature infants less than 33 weeks gestational age, less than 1750 grams birth weight, and less than 24 hours of age who require mechanical ventilation for treatment of RDS. Patients will be separated into four categories by birth weight and then randomly assigned to one of three treatment groups: CV only, HFOV initially followed by CV, or HFOV only.

Progress: This study was terminated due to inability of the investigators to complete the training in high frequency oscillatory ventilation.

# Detail Summary Sheet

Date: 8 Aug 90 Proj No: C-22-86 Status: Completed  
 Title: Prophylactic Intravenous Immunoglobulin in High Risk Neonates.  
 (Collaborative Study with Walter Reed Army Medical Center)

Start Date 26 Feb 86	Est Comp Date:
Principal Investigator (vice Wiswell) Jan Carter, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Leonard E. Weisman, LTC, MC John Woodall, COL, MC Howrd Heiman, MAJ, MC
Key Words: Neonate, high risk	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 7	
Total Number of Subjects Enrolled to Date: 32	
Date of Periodic Review 12 Mar 90	Results Continue

Objective(s): To evaluate, in a double blind manner, the effectiveness, compared to an albumin placebo, of IVIG in preventing infectious disease and/or reducing morbidity and mortality in the high risk neonate.

Technical Approach: Participants will be given one of two medications. One will contain antibody to Group B streptococci and the other will contain human albumin and sugar. One dose of the medication will be given by vein over a one hour period. 2 cc. of blood will be drawn before the medicine is given, immediately after it is given, and at one, two, and eight weeks later. Babies will be followed over an 8 weeks period for evidence of infection.

Progress: No adverse reactions have been observed. Prophylactic intravenous immunoglobulin was found to be effective therapy in reducing morbidity and mortality in high risk neonates.

# Detail Summary Sheet

Date: 26 Oct 90 Proj No: C-79-87 Status: Ongoing  
 Title: Appetite and Pectin

Start Date 9 Sep 87	Est Comp Date:
Principal Investigator Chandra M. Tiwary, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Victor Elysee, SGT
Key Words: Appetite Obesity	
Accumulative MEDCARE Cost:	Est Accumulative OMA Cost: 650.00
Number of Subjects Enrolled During Reporting Period: 23	
Total Number of Subjects Enrolled to Date: 23	
Date of Periodic Review 15 Oct 88	Results Continue

Objective(s): To assess the role of pectin in suppression of hunger in obese children.

Technical Approach: Subjects will be obese children (ages 6-18) attending the pediatric clinic. All subjects will be studied twice at least 3 days apart. Subjects will be given either orange juice or orange juice with pectin. The child will be asked to describe the degree of hunger on a scale of 1 to 20, giving a rating of 1 if most full and 20 if very hungry. The same scale will be used to rate hunger every hour for four hours. At the end of four hours, the child will be given ice cream and again asked to rate hunger. Saliva production will be measured on three times - before drinking the juice, 4 hours after drinking the juice, and 1/2 hour after eating the ice cream.

Progress: No new patients have been enrolled in this study since the last report. It is anticipated that an additional seven patients will be adequate to complete the study which should be accomplished within the next year.

# Detail Summary Sheet

Date: 18 Sep 90 Proj No: C-24-88 Status: Ongoing  
 Title: Ceftriaxone for Outpatient Management of Suspected Occult Bacteremia

Start Date 13 Jan 88	Est Comp Date:
Principal Investigator	Facility
James H. Brien, LTC, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Pediatrics	Robert L. Norris, Jr., MAJ, MC
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 66	
Date of Periodic Review 3 Apr 90	Results Continue

Objective(s): To determine the effectiveness of Ceftriaxone in the outpatient management of children three to thirty-six months of age with suspected occult bacteremia.

Technical Approach: Children are randomized to receive either Ceftriaxone IM or Augmentin PO with ongoing follow-up until fever and illness is resolved.

Progress: Patient enrollment continues at all participating medical centers. At present there are >400 patients enrolled on the study.

# Detail Summary Sheet

Date: 18 Sep 90 Proj No: C-90-88 Status: Ongoing  
 Title: Phase I Study of Piritrexim in Children with Advanced Leukemia and Solid Tumors (A Multicenter Study under the Direction of Dr. Thomas E. Williams, Santa Rosa Childrens Hospital)

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia	Timothy J. O'Rourke, LTC, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 29 Jan 90	Results Continue

Objective(s): To define the maximum tolerated dose and the dose limiting toxicity when Piritrexim capsules are administered orally to children in a daily x 5 schedule repeated every three weeks.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Although no patients have been entered, we would like to have the drug available in the event a patient should be eligible for inclusion in the study.



# Detail Summary Sheet

Date: 17 Oct 89	Proj No: C-96-89	Status: Completed
Title: A Practical Microtechnique for Protine, Partial Thromboplastin Time and Fibrinogen in the Neonate		

Start Date: 1 Aug 89	Est Comp Date:
Principal Investigator	Facility
Sheryl J. Morris, CPT, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Pediatrics	Howard Heiman, MAJ, MC
Key Words:	Jan Carter, MAJ, MC
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To evaluate a new microtechnique for determining protine, partial thromboplastin time, and fibrinogen.

Technical Approach: At presentation of labor, the obstetrical service obtains permission for delivery. Inclusive is utilization or disposal of any tissue or blood products. The general practice is disposal of the placenta and cord blood. This study evaluated the accuracy of a simple modification of a standard container to accommodate a smaller sample volume for determination of the prothrombin time (PT), partial thromboplastin time (PTT) and fibrinogen. These tests were chosen secondary to current use of the standard tube for the neonate. The standard container consisted of 2.7 ml of blood and 0.3 ml of anticoagulant. The anticoagulant was aspirated from a second tube with 0.15 ml returned in addition to 1.35 ml of cord blood.

Progress: Statistical analysis of the standard versus modified tube results using Pearson's correlation coefficients showed (r) values > 0.70 with p values << 0.001. Hematocrit had no significant effect on results over the range of hematocrits tested. Standardized residual analysis demonstrated no clinically significant outliers. Use of the modified container for a coagulation profile offers an economic advantage to investment in microtubes, equipment and personnel training for a small population of patients. In addition, it may be speculated that by decreasing iatrogenic blood loss in the neonate, a decreased frequency of blood transfusions may be seen.

# Detail Summary Sheet

Date: 17 Oct 90 Proj No: C-37-90 Status: Ongoing  
 Title: The Incidence of Congenital Respiratory Syncytial Virus.

Start Date 12 Mar 90	Est Comp Date:
Principal Investigator (vice Geddie) Howard S. Heiman, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Jan Carter, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): A prospective study to determine if respiratory syncytial virus can be transmitted congenitally, and the incidence of RSV in the newborn population. Study population will include all women who deliver at Brooke Army Medical Center and their newborns, both term and premature.

Technical Approach: All newborns will receive routine DeLee suctioning of oral and nasopharynx on the perineum or abdomen by obstetrics. The specimen will be sent to the area lab for RSV ELISA. On all newborns who are RSV ELISA positive, acute and convalescent serum titers for RSV will be obtained.

Progress: Since this is a seasonal condition, no subjects have been enrolled.

# Detail Summary Sheet

Date: 3 Oct 90 Proj No: C-54-90 Status: Ongoing  
 Title: EXOSURF Pediatric Sterile Powder for Treatment of Respiratory Distress Syndrome.

Start Date 24 Apr 90	Est Comp Date:
Principal Investigator Jan Carter, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Howard S. Heiman, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): a) TREATMENT COMPONENT A: 1) to provide prophylactic treatment with EXOSURF Pediatric to middle sized premature infants who are likely to benefit from its use, and for whom no satisfactory alternative treatment is available. 2) to identify serious, unexpected adverse events associated with the prophylactic use of EXOSURF Pediatric in middle-sized babies. 3) to monitor the survival and acute clinical course through 28 days of life, death, or hospital discharge or transfer in middle-sized infants who receive EXOSURF Pediatric prophylactically. b) TREATMENT COMPONENT B: 1) to provide EXOSURF Pediatric to middle-sized babies with established RDS who are likely to benefit from the use of EXOSURF Pediatric and for whom no satisfactory alternative is available. 2) to identify serious, unexpected adverse events associated with the rescue use of EXOSURF Pediatric in middle-sized babies. 3) to monitor survival and acute clinical course through 28 days of life, death, or hospital discharge or transfer of middle-sized infants with established RDS who receive rescue EXOSURF Pediatric. c) TREATMENT COMPONENT C: 1) to provide EXOSURF Pediatric to large babies with established RDS who are likely to benefit from its use and for whom no satisfactory alternative treatment is available. 2) to identify serious, unexpected adverse events associated with the rescue use of EXOSURF Pediatric in large babies with established RDS. 3) to monitor the survival and acute clinical course through 28 days of life, death, or hospital discharge or transfer of large infantss with established RDS who receive EXOSURF Pediatric. This Protocol has been reviewed and approved by FDA.

Technical Approach: Patients meeting the criteria for inclusion outlined above, will be treated as outlined in the study protocol.

Progress: Since obtaining approval, no patients have been eligible for entry on this study.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-62-90 Status: Ongoing  
 Title: High-Dose Chemotherapy with Autologous Bone Marrow Rescue in Children with Recurrent or Progressive Solid Tumors or Primary CNS Malignancies: A Phase II Study (Collaborative Study with Walter Reed Army Medical Center)

Start Date 15 May 90	Est Comp Date:
Principal Investigator Allan R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Glenn Edwards, MAJ, MC, WRAMC David Maybee, COL MC, WRAMC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To define the toxicities of a regimen of high-dose cyclophosphamide (CY), etoposide (VP-16), and carboplatin (CBDCA) with autologous bone marrow infusion in pediatric patients with recurrent or progressive CNS neoplasms or solid tumors.

2) To measure response rates in a group of patients with refractory solid tumors and CNS malignancies following high-dose chemotherapy and autologous bone marrow infusion.

Technical Approach: To be eligible for this study, patients must be < 21 years of age, have an estimated survival of at least 8 weeks, and have adequate blood counts prior to bone marrow harvest. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been eligible for inclusion in this study.

# Detail Summary Sheet

Date: 18 Sep 90 Proj No: C-12-77 Status: Ongoing  
 Title: Intravenous Administration of I<sup>131</sup> (NP 59) for Adrenal Evaluation of Imaging.

Start Date 15 Nov 76	Est Comp Date:
Principal Investigator(vice Hartshorne) James D. Hieronimus, LTC, USAF MC	Facility Brooke Army Medical Center
Dept/Svc Department Radiology/Nuclear Medicine	Associate Investigators:
Key Words: Adrenal scan	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 13	
Date of Periodic Review 10 Sep 90	Results Continue

Objective(s): Clinical evaluation of NP 59 as a diagnostic agent for the detection of adrenal-cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla.

Technical Approach: This study will be performed on 50 patients after complete evaluation by the Endocrinology Service. The radiopharmaceutical will be administered by slow IV injection with a dose of 1mCi in adults and 15µCi/kg in children. Lugol's solution, 5 drops twice daily starting one day before injection and continuing for two weeks, will be used to block thyroid uptake of radioiodine. Images will be obtained on the 4th, 7th, and 11th day following injection using scintillation camera.

Progress: Clinical correlation with scan findings has been good indicating both good sensitivity and specificity of this agent for adrenal adenoma or bilateral adrenal hyperplasia (though small population).

# Detail Summary Sheet

Date: 18 Sep 90 Proj No: C-47-89 Status: Ongoing  
 Title: Evaluation of <sup>131</sup>I-miBG (<sup>131</sup>I-meta-iodobenzylguanidine sulfate) in Patients Suspected of Having Pheochromocytoma, Paraganglioma or Medullary Hyperplasia

Start Date 20 Mar 89	Est Comp Date:
Principal Investigator James D. Heironimus, Lt Col, USAF, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Radiology/Nuclear Med.	Associate Investigators: Vincent D. Pearson, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 6	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review 29 Jan 90	Results Continue

Objective(s): To evaluate the use of <sup>131</sup>I-miBG as an aid in the diagnosis, evaluation, and localization of pheochromocytomas, paraganglioma, neuroblastoma and/or adrenal medullary hyperplasia.

Technical Approach: Patients suspected of having pheochromocytoma, paraganglioma or medullary hyperplasia will be eligible. If upon careful consideration of the clinical history, examination and laboratory findings the patient is considered to have reasonable suspicion (>5% possibility) of any of the above conditions, they will be included for study by <sup>131</sup>I-miBG scintigraphy.

Progress: Negative studies for pheochromocytoma have correlated well with clinical and anatomic imaging data, but lacking positive case at this time. Limited use with neuroblastoma has correlated well. Used once to detect a pancreatic islet cell tumor with negative results which correlated with known clinical data.

# Detail Summary Sheet

Date: 22 Aug 90 Proj No: C-58-89 Status: Terminated  
 Title: Neuroimaging in Tourette Syndrome

Start Date: 4 Apr 89	Est Comp Date:
Principal Investigator James H. Timmons, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Radiology/Nuclear Med.	Associate Investigators:
Key Words: Tourette Syndrome	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 11 May 90 Results Terminate	

Objective(s): To evaluate the effectiveness of Naltrexone in controlling the disabling movements of Gilles de la Tourette Syndrome (TS), and to assess neurotransmitter function in TS both while on Naltrexone and off medication.

To determine if abnormalities exist of function or regional blood flow in brains of patients with Gilles de la Tourette syndrome (TS).

Technical Approach: Several studies have attempted to look at neuroanatomic abnormalities in TS. In one of these two patients were reported with midbrain abnormalities found on MRI. SPECT is a new technique of function brain imaging and has been successfully used to evaluate several neurologic conditions. Iofetamine has the effect of a slow intra-arterial injection and continues to reach the brain over the entire period of the scan. Therefore, patients meeting the criteria for inclusion of the above study will be referred to the Nuclear Medicine Service for scanning. 3-5 millicuries of I-123 Iofetamine will be administered IV and the imaging obtained using SPECT.

Progress: This study was terminated due to inability to obtain adequate number of patients.

# Detail Summary Sheet

Date: 26 Sep 90 Proj No: C-62-89 Status: Completed  
 Title: Evaluation of the Effects of Treatment with 0.075% Topical Capsaicin in Patients with Reflex Sympathetic Dystrophy Using Three Phase Bone Scintigraphy

Start Date: 11 Apr 89	Est Comp Date:
Principal Investigator Mary Hart, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Radiology/Nuclear Med.	Associate Investigators: Stuart Sinoff, MAJ, MC Emil Menk, MAJ, MC
Key Words: Reflex sympathetic dystrophy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 6	
Total Number of Subjects Enrolled to Date: 10	
Date of Periodic Review	Results

Objective(s): 1) To assess the efficacy and safety of topically applied capsaicin cream 0.075% in the treatment of pain symptoms of reflex sympathetic dystrophy (RSD) or causalgia.

2) To assess if the treatment of superficial pain results in the improvement of or reversal of concurrent bone pathology.

3) To assess the usefulness of bone scintigraphy in predicting responses to treatment with capsaicin.

4) To assess the usefulness of bone scintigraphy as an objective indicator of response to capsaicin cream.

Technical Approach: Ten patients with chronic RSD or causalgia were entered into this clinical trial. Eight patients had RSDA or Partial RSDA with incomplete and unsatisfactory response to ganglion blockade. Symptom severity and disability was assessed through the physicians global evaluation and visual analogue scale. Pretreatment assessment included three phase radionuclide bone scanning. Each patient received four 1.5 ounce tubes of capsaicin cream to be applied four times daily for the duration of the study.

Progress: Seven patients completed the study and all but one demonstrated a significant clinical response as measured by visual analogue scales of pain, and pain relief, and changes in categorical pain scale and physicians global evaluation.

A new study, C-56-90, will evaluate the effectiveness of capsaicin in the control of dysesthetic pain syndromes.



# Detail Summary Sheet

Date: 22 Aug 90	Proj No: C-108-89	Status: Ongoing
Title: Evaluation of Interstitial Lymphoscintigraphy with Radioactive Technetium Antimony Trisulfide Colloid (99m Tc-Sb <sub>2</sub> S <sub>3</sub> ) for Lymphedema, Internal Mammary and Excised Malignant Melanoma Lymphoscintigraphy		

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator James D. Heironimus, Lt Col, USAF MC	Facility Brooke Army Medical Center
Dept/Svc Department of Radiology/Nuclear Med.	Associate Investigators: M. Oyewole Toney, LTC, MC Mayola W. Boykin, MAJ, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 12 Sep 90	Results Continue

Objective(s): To determine the effectiveness of radioactive Tc99m Antimony Trisulfide Colloid in imaging lymph nodes.

Technical Approach: Patients will be selected and referred to Nuclear Medicine Service primarily by the Surgery and Oncology Clinic. For evaluation for lymphedema, intradermal injections of the radiopharmaceutical will be made in the distal extremities of interest. To evaluate the lymph drainage paths of a dermal region, injections will be mde intradermally immediately adjacent to the site of the skin lesion/biopsy site. For all studies, scintigraphic imaging will be performed using an Anger Gamma Camera system. Multiple use of the appropriate areas will be attained immediately following the injeciton of the radiopharmaceutical as well as approximately 2-4 hours after injection. Body outlining and/or flood field imaging techniques will be performed to provide additional positional information.

Progress: One study has been done to date and the results of this study were unambiguous and played a significant role in medical planning for the patient. The imaging study performed clearly displayed the lymphatic drainage of the biopsy skin site to three lymph node regions. Clinician awareness of this procedure and its potential diagnostic benefits has been a principle factor in the limited use of this radiopharmaceutical to date.

# Detail Summary Sheet

Date: 26 Sep 90 Proj No: C-126-89 Status: Ongoing  
 Title: HM-PAO Brain SPECT in TIA as Predictor of Ischemic Infarction

Start Date: 31 Oct 89	Est Comp Date:
Principal Investigator (vice Sinoff) James Heironimus, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Radiology/Nuclear Med.	Associate Investigators: Mary B. Hart, MAJ, MC Alan Halliday, MAJ, MC Wayne Gordon, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To prospectively investigate the usefulness of HM-PAO Brain SPECT as a predictor of permanent cerebral infarction in transient ischemic attacks.

Technical Approach: In a prospective series of patients presenting with transient cerebral ischemia, Tc-99m HM-PAO brain SPECT studies will be obtained within 72 hours (of the TIA) and follow the clinical course over a three month period. Following Tc-99m HM-PAO SPECT the patients will be followed by one of the neurologists at six weeks and three months.

Progress: It is hoped that patients referrals will begin in the near future.

# Detail Summary Sheet

Date: 17 Oct 90 Proj No: C-33-90 Status: Terminated  
 Title: Peripheral Laser Angioplasty.

Start Date 13 Feb 90	Est Comp Date:
Principal Investigator	Facility
David McFarland, MAJ	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Radiology	
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To study the safety and efficacy of peripheral laser angioplasty with the LASTAC System.

Technical Approach: Patients with lifestyle-limiting claudication will undergo peripheral arteriography. If the patient is a candidate for balloon angioplasty, that procedure will be offered. If unable to cross the lesion with angioplasty equipment, laser angioplasty will be attempted, followed by angioplasty and/or atherectomy. Approximately 20 patients will undergo laser angioplasty after which results will be analyzed.

Progress: This study was terminated due to failure to obtain the LASTAC System.

# Detail Summary Sheet

Date: 27 Sep 90	Proj No: C-43-90	Status: Ongoing
Title: Renovascular Hypertension Screening		

Start Date 27 Mar 90	Est Comp Date:
Principal Investigator Paul A. Neese, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Radiology	Associate Investigators: Ronald Salmond, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 9	
Total Number of Subjects Enrolled to Date: 9	
Date of Periodic Review	Results

Objective(s): To determine if minimally invasive screening tests can improve the detection of renovascular hypertension and provide prognostic information for revascularization procedures.

Technical Approach: Patients meeting the criteria for inclusion will be withdrawn from antihypertensive while under medical supervision. They will then have baseline and Captopril stimulated peripheral vein renin determinations, as well as a Captopril Renogram. This will be followed by baseline and Captopril renal vein renin sampling and renal arteriography. If a significant lesion is found at arteriography, a revascularization procedure will be offered. Patients undergoing revascularization will have a follow-up Captopril renogram.

Progress: Nine subjects have been enrolled to date. Two subjects were withdrawn by the associate investigator because of associated medical illnesses which have required other diagnostic evaluations. It is hoped that when these patients have completed evaluation of their other medical conditions that they will remain candidates for study enrollment. The only adverse reactions encountered during this study period has been symptomatic hypotension in two patients during the oral capoten stimulation test. There were no sequelae of the transient hypotension. Both episodes occurred in patients who had subsequently confirmed renin dependent hypertension due to unilateral renal artery stenosis and unilateral renal parenchymal disease. The percent frequency of symptomatic hypotension seen with this test in patients with subsequent confirmed renin dependent hypertension is similar to that which has previously been described in the medical literature. The small number of patients studied to date does not allow meaningful statistical analysis.

C-43-90 (continued)

No new information bearing on the willingness of subjects to participate in this study has been obtained. The major difficulty to date has been obtaining the number of study candidates which are available in our patient population. This has been due to failure of physicians to refer potential study candidates. This problem is not unique to our study and complicates many prospective studies which require large patient numbers and invasive diagnostic procedures. We are attempting to remedy this problem by increasing the dissemination of the study inclusion and exclusion criteria.

# Detail Summary Sheet

Date: 20 Sep 90 Proj No: C-21-78 Status: Completed  
 Title: Clinical Study of Intraocular Lenses (Alcon, 3M, Surgidev, Storz)

Start Date February 1978	Est Comp Date:
Principal Investigator (vice Walker) Calvin E. Mein, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators:
Key Words: Intraocular lens Cataract extraction	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 2535	
Date of Periodic Review 23 Mar 90 Results Continue	

Objective(s): To establish the safety and effectiveness of this device for use in human subjects according to guidelines recommended by the Food and Drug Administration ophthalmic advisory panel.

Technical Approach: Intraocular lenses are implanted according to the company protocol.

Progress: Only FDA approved lenses are being implanted at this time. If at some time in the future an investigational lens is needed, a new protocol will be submitted.

# Detail Summary Sheet

Date: 14 Aug 90 Proj No: C-70-85 Status: Completed  
 Title: High Frequency Hearing Levels in Otherwise Healthy Children Exposed to Three or More In Utero Diagnostic Ultrasounds

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator (vice Aspinall) Donald R. Bender, LTC, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators:
Key Words: High frequency hearing levels	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 34	
Date of Periodic Review 8 Sep 90	Results Completed

Objective(s): 1) To establish a normal value for high frequency hearing thresholds in children.

2) To compare a control group of healthy children with "normal" hearing threshold to a group of healthy children exposed to three or more in utero ultrasounds.

Technical Approach: Thirty-four subjects ranging in age from 6 to 13 years were evenly divided into two groups of 17 each. The mean age for the control and experimental groups was 9.4 and 8.8 years, respectively. There were 10 females and 7 males in the control group while the experimental group consisted 8 females and 9 males. The control group had no ultrasound exposures in utero while the experimental group consisted of subjects whose parents reported three or more exposures in utero.

All subjects were determined to have hearing within normal limits in the 250 to 8000 Hz frequency range; i.e., thresholds less than 25 dB. They were also otoscopically evaluated by an otologist and deemed free of ear disease prior to inclusion in the study.

A commercially available Demlar model 20k extended high frequency audiometer with Koss HV/IA dynamic earphones served as the stimulus source. All tests were conducted in an IAC sound suite.

Thresholds for pure tones of 8, 10, 12, 14, 16, 17, 18, 19, and 20 kHz were obtained on both ears of all subjects. Relative measurements were made in 5 dB increments in ascending frequency.

C-70-85 (continued)

Progress: Although substantial intersubject variability existed between the control and experimental groups, a comparison of mean data yielded no statistically significant differences. It appears that ultrasound exposures in utero does not have a measurable deleterious effect on ultra high frequency hearing sensitivity.



# Detail Summary Sheet

Date: 14 Sep 90      Proj No: C-1-86      Status: Ongoing  
 Title: Continuous Intra-Arterial Chemotherapy for Advanced Refractory Pelvic Malignancies Employing an Implantable Infusion System

Start Date 28 Oct 85	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Francisco Rodriguez, COL, MC
Key Words: Infusion System, implantable	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 29 Jan 90	Results      Continue

Objective(s): To determine the efficacy of continuous infusion of intraarterial chemotherapeutic agents for pelvic malignancies utilizing an implantable infusion system (Porta-Cath)®.

Technical Approach: Patients with advanced pelvic malignancies are eligible. After analysis of feeding tumor vessels from the digital subtraction angiography, a decision will be made as to which hypogastric vessel supplies the majority of the tumor. An oblique, lower quadrant incision will be made on the appropriate side and the hypogastric artery and its proximal branches will be dissected extraperitoneally. The lumen will be dilated and the catheter directed into the hypogastric artery. The tip of the catheter will be placed immediately above the highest vessel off which tumor vessels arise.

Progress: No patients have been encountered during the past year who meet the criterion for inclusion in this study. It is recommended that the study be kept open in the event that such a patients is referred to the Urology Service at BAMC.

### Detail Summary Sheet

Date: 21 Sep 89	Proj No: C-73-86	Status: Completed
Title: Comparison of External Pneumatic Compression Boots and Embolex in Prophylaxis Against Deep Vein Thrombosis		

Start Date 12 August 1986	Est Comp Date:
Principal Investigator (vice Hansberry) Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Oncology	Associate Investigators: John M. Bauman, MAJ, MC Francisco Rodriguez, COL, MC
Key Words: Thrombosis, deep vein	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 76	
Total Number of Subjects Enrolled to Date: 76	
Date of Periodic Review 9 Sep 88	Results Continue

Objective(s): To compare the efficacy and complication rates of external pneumatic compression (EPC) boots and the drug Embolex in preventing lower extremity venous thrombosis in patients undergoing open urologic procedures.

Technical Approach: Adult male patients 40 years of age and older scheduled for open urologic procedures are eligible. Patients will be assigned to one of three treatment groups according to a table of random numbers. Group I will receive Embolex 2 hours before and every 12 hours during the post-operative period. Group II will have external pneumatic compression of the calves achieved by inflatable boots. EPC will be applied during induction of anesthesia and continued until the patient is ambulatory at least three times a day. Controls will wear Ted hose pre- and post-operatively.

Progress: Thromboembolic phenomena occurred in 20% of patients treated with TED hose, in 12.5% of patients treated with external pneumatic compression boots and in 8% of patients treated with Embolex.

# Detail Summary Sheet

Date: 20 Aug 90 Proj No: C-87-86 Status: Terminated  
 Title: LCSG 853 - A Clinical Trial in Patients with Stage II and III Completely Resected Non-Small Cell Lung Cancer Comparing Chemotherapy (CAT) versus No Therapy Following Surgery...

Start Date 8 Sep 86	Est Comp Date:
Principal Investigator (vice Grishkin) James Ameika, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators: Greg Bowman, LTC, MC Dennis Moritz, LTC, MC Robert Johnson, MAJ, MC
Key Words: Cancer, non-small cell lung	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 12 Sep 90	Results Terminated

Objective(s): 1) To compare combination chemotherapy (CAP given at 4-week intervals for 4 cycles) as an adjuvant to surgery to prolong disease-free interval and survival with no immediate adjuvant treatment following complete resection of stage II and III non-small cell cancer of the lung.

2) To compare combination chemotherapy (CAP) administered immediately post-operatively in prolonging survival in these patients with delayed combination chemotherapy administered at the time of systemic recurrence in the no-treatment control group.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No new patients have been enrolled. This study was terminated due to closure of the Lung Cancer Study Group.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-3-87 Status: Ongoing  
 Title: Radical Retropubic Prostatectomy and Orchiectomy for Stage C Carcinoma of Prostate

Start Date 19 Nov 87	Est Comp Date:
Principal Investigator(vice Brizzolara) Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators:
Key Words: Prostate Carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 29 Jan 90 Results Continue	

Objective(s): To determine the efficacy of combined hormonal and surgical therapy for carcinoma of the prostate.

Technical Approach: Patients eligible for entry into the study will either be placed on Leupron therapy, one injection per day for two months, or undergo bilateral simple orchiectomy. Eight weeks following orchiectomy, radical prostatectomy will be performed.

After post-hormonal manipulation studies are obtained, patients will undergo staging pelvic lymphadenectomy. Postoperative treatment shall be in accordance with standard procedures.

Progress: The long-term follow-up of the four patients who are currently on-study is continuing. Although two patients were referred to BAMC for evaluation for this study, neither elected to participate. The four patients from BAMC as well as six patients from the University of Oregon similarly treated were the subject of a presentation at a workshop on carcinoma of the prostate at Snowbird, UT in July 1990. It appears that local control may be possible but that many of these patients will either not downstage or will suffer subsequent disease recurrent. (The results of the initial group of patients were published in the proceedings of the workshop.)

# Detail Summary Sheet

Date: 3 Jan 90	Proj No: C-46-87	Status: Terminated
Title: LCSG 862 - Immunohistochemical Analysis of Lung Cancer		

Start Date 9 Apr 87	Est Comp Date:
Principal Investigator (vice Grishkin) Greg T. Bowman, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To ascertain the predictive value of a series of immuno-histochemical markers for response and survival in a previously studied patient population on whom data on routine prognostic factors, response, survival and toxicity is known.

2) To ascertain whether patterns of disease presentation are correlated with specific markers for cell surface and cytoskeletal proteins.

3) To ascertain if the pattern of loss of markers used to define the small cell "variant" cell lines and specimens is predictive of improved response in non-small cell patients.

Technical Approach: Data collection and registration are as outlined in the study protocol.

Progress: This study was terminated due to closure of the Lung Cancer Study Group.

# Detail Summary Sheet

Date: 14 Sep 90	Proj No: C-50-87	Status: Ongoing
Title: Chromosomal Analysis of Genitourinary Neoplasms		

Start Date 11 May 87	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Eric J. Zeidman, MAJ, MC Kurt L. Hansberry, CPT, MC Isidoro Chapa, GS-7
Key Words: Karyotype	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 16,753.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To correlate tumor karyotypes with patient data, tumor stage and grade, and clinical course of the disease.

Technical Approach: At the time of removal of a genitourinary tumor, a small piece of tumor tissue will be sent for karyotyping. The technique for karyotyping will employ the coverslip method. Chromosomal banding will include standard techniques for G-banding, Q-banding (fluorescence), and C-banding. Photographs will include intact banded metaphase plates. Karyotyping will be performed by cutting individual chromosomes from photographs and identifying according to standard nomenclature.

Progress: A number of patients with benign prostates have undergone cytogenetic analysis. On many of these patients, unfortunately, incomplete karyotypes have been encountered. Through improved cell harvesting techniques it is hoped that more complete spreads can be acquired.

# Detail Summary Sheet

Date: 25 Sep 90	Proj No: C-90-87	Status: Ongoing
Title: Opti-Fix <sup>tm</sup> Hip Prosthesis (Multicenter Study)		

Start Date 21 Sep 87	Est Comp Date:
Principal Investigator Allen L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators:
Key Words: Prosthesis, hip	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date: 10	
Date of Periodic Review 10 Sep 89	Results Continue

Objective(s): To prove safety and efficacy of the use of porous surfaces (with stability afforded by biologic fixation instead of bone cement) by statistical comparison to similar patient populations of like cemented components and other published data.

Technical Approach: Patients requiring total hip replacement will be asked to participate in this study. If they agree, the Opti-Fix<sup>tm</sup> will be implanted as outlined in the study protocol.

Progress: Follow-up of the ten patients continues. There have been no complications.

# Detail Summary Sheet

Date: 14 Sep 90      Proj No: C-10-88      Status: Completed  
 Title: C-Reactive Protein, Erythrocyte Sedimentation Rate, and White Blood  
 Count in Aseptic Loosening of Total Joint Components

Start Date 2 Dec 87	Est Comp Date:
Principal Investigator Henry G. Chambers, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Allan L. Bucknell, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 391.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 29 Jan 90	Results      Continue

Objective(s): To prospectively evaluate the efficacy of these blood tests in the evaluation of pre- and postoperative revision total joint patients.

Technical Approach: All patients who enter the hospital for a revision total joint arthroplasty will have a CRP, ESR, and WBC level drawn at the time of initial routine preoperative evaluation. These will be repeated immediately postoperatively, on postoperative days 1 thru 5, at 6 weeks, at 3 months and at 6 months. Should an infection be suspected clinically, a CRP level will be drawn at that time as well.

Progress: There were too many missing data points in the postoperative patients to make this study worthwhile. The patients would not wait for the several hours in the laboratory to have their blood drawn after waiting three hours in the X-ray department. Therefore, the study was abandoned.



# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-12-88 Status: Completed  
 Title: The Effect of Bone Allograft in Total Joint Replacement on C-Reactive Protein, Erythrocyte Sedimentation Rate, and White Blood Cell Count.

Start Date 2 Dec 87	Est Comp Date:
Principal Investigator Henry G. Chambers, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Allan L. Bucknell, COL, MC
Key Words: Bone allograft	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 135.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To prospectively evaluate the efficacy of these blood tests in the evaluation of patients undergoing total joint replacement with bone allograft.

Technical Approach: All patients who enter the hospital for a total joint arthroplasty in whom an allograft is planned will have a CRP, ESR, and WBC level drawn at the time of initial routine preoperative evaluation. These will be repeated immediately postoperatively, on postoperative days 1 thru 5, at 6 weeks, at 3 months and at 6 months. Should an infection be suspected clinically, a CRP level will be drawn at that time as well.

Progress: There were too many missing data points in the postoperative patients to make this study worthwhile. The patients would not wait for the several hours in the laboratory to have their blood drawn after waiting three hours in x-ray department. Therefore, the study was abandoned.

# Detail Summary Sheet

Date: 20 Aug 90 Proj No: C-20-88 Status: Terminated  
 Title: LCSG 871 - Centralized Non-Small Cell Lung Cancer Specimen Repository  
 and DNA/RNA Bank

Start Date 13 Jan 88	Est Comp Date:
Principal Investigator (vice Grishkin) James Ameika, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators: Dennis Moritz, LTC, MC Greg Bowman, LTC, MC Robert Johnson, MAJ, MC
Key Words: Non-small cell lung cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 17	
Date of Periodic Review 12 Sep 90	Results Terminate

Objective(s): To provide the LCSG tissue repository with specimens of non-small cell lung cancer and adjacent normal tissue from previously untreated patients who are undergoing resection of lung cancer.

Technical Approach: Patients with non-small cell lung cancer, who have not received prior treatment, who undergo resectional therapy, will be invited to participate. At the time of operation, if sufficient tissue is available, portions of the primary tumor and adjacent normal lung tissue will be processed as outlined in the study protocol.

Progress: This study was terminated due to closure of the Lung Cancer Study Group.

# Detail Summary Sheet

Date: 20 Sep 90 Proj No: 2-88 Status: Terminated  
 Title: In vivo Monitoring of Reconstructive Hip Joints During Walking

Start Date 17 Feb 88	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: James A. Davidson, M.S. Henry G. Chambers, MAJ, MC Michael H. Haak, CPT, MC
Key Words: Reconstructed hip joint	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 6 Mar 80 Results Continue	

Objective(s): To determine the activity the activity associated change in temperature in vivo for total hip replacement arthroplasty.

Technical Approach: A thermocouple will be placed in the hip joints of patients who have received a total hip arthroplasty with either a cobalt-chrome hip or a ceramic head to evaluate if there is any change in hip temperature.

Progress: Multiple attempts at placing the catheter in cadavers in the appropriate location have failed. Therefore, the study is terminated.

# Detail Summary Sheet

Date: 18 Jul 90 Proj No: C-29-88 Status: Completed  
 Title: Evaluation of Arthroplasty-Associated Bone Density Changes with Dual Photon Absorptiometry.

Start Date 17 Feb 88	Est Comp Date:
Principal Investigator Michael H. Haak, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: Allan L. Bucknell, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 80	
Date of Periodic Review 6 Apr 89	Results Continue

Objective(s): To evaluate the bone mineral density and associated strength of bone in patients undergoing total hip replacement arthroplasty.

Technical Approach: Forty active duty military subjects with acute, bone scintigraphy-proven lower extremity stress fractures were evaluated and compared to matched controls. The study group had clinical examination, serum calcium and phosphate studies, dietary survey, technetium 99m methylene diphosphonate bone scan, and for those with stress fractures, dual photon abroptiometry of their lumbar spine fo assess systemic bone mass.

Progress: Mean systemic bone mass was 90% of normal (ranges 104%-78%) compared to age, sex, race, height, and weight matched controls ( $p < .01$ ). This association of lowered bone mineral content in these patients with stress fractures may identify a group at risk. Further work-up to exclude metabolic bone disease may be warranted. These individuals with stress fractures may benefit from exercise prescription to prevent further or recurrent injury.

# Detail Summary Sheet

Date: 20 Sep 90 Proj No: C-30-88 Status: Terminated  
 Title: Functional Evaluation of Morbidity with Upper Extremity Arterial Catheterization

Start Date 17 Feb 88	Est Comp Date:
Principal Investigator Michael H. Haak, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: Richard Jansen, CPT, MS William Wright, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 277.55
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 20	
Date of Periodic Review 6 Mar 90	Results Continue

Objective(s): To evaluate the morbidity associated upper extremity arterial catheterization with prospective subjective and objective functional upper extremity evaluation of patients receiving elective cardiac catheterization.

Technical Approach: Patients undergoing catheterization will have pre-cath and interval evaluation of upper extremity function.

Progress: Primary investigator has departed BAMC. No one interested in continuing study; therefore it should be terminated.

# Detail Summary Sheet

Date: 22 Aug 90 Proj No: C-38-88 Status: Terminated  
 Title: Bone Density Changes with Compression Plating of Fractures

Start Date 7 Mar 88	Est Comp Date:
Principal Investigator Rick D. Compton, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: Michael H. Haak, CPT, MC Edwin Melendez, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 9	
Date of Periodic Review 23 Mar 90	Results Terminated

Objective(s): Patients undergoing removal of compression plates after treatment of fractures will undergo bone densitometry of involved and uninvolved sites. Bone density changes will be plotted versus time since plating for various bones to quantify plate associated bone density loss.

Technical Approach: Dual photon absorptiometry will be utilized after plate removal to determine if bone density can be associated with plating of fractures as compared to the uninjured side.

Progress: Scans were technically unacceptable; therefore the study was terminated.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-39-88 Status: Ongoing  
 Title: Evaluation of Constituents in the Synovial Fluid of Reconstructed Hips

Start Date 29 Mar 88	Est Comp Date:
Principal Investigator Henry G. Chambers, MAJ, MC	Facility Brooke Army Medical Center
Dept/Unit Department of Surgery/Orthopaedic	Associate Investigators: Allan L. Bucknell, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 6 Mar 90 Results Continue	

Objective(s): Evaluation of constituents in the synovial fluid of reconstructed hips.

Technical Approach: Twenty patients with reconstructed hips will have samples of synovial fluid collected. Each sample will be evaluated for hyaluronic acid, cholesterol, and glucose concentration.

Progress: The study itself is completed. The synovial fluid has been forwarded to Emory University School of Medicine where they are completing the study.

# Detail Summary Sheet

Date: 15 May 90 Proj No: C-52-88 Status: Completed  
 Title: Multiclinic Trial of Fibrillar Collagen/Calcium Phosphate Ceramic (COLHAP)

Start Date 9 May 88	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: Henry G. Chambers, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 14 May 90 Results Completed	

Objective(s): To determine the efficacy (functional and roentgenographic results) and benefits of COLHAP bone marrow (CBGS) when used for grafting procedures of long bones; to determine the safety of COLHAP (the incidence of significant device-related reactions); and to compare the efficacy and safety of COLHAP with standard autografting procedures.

Technical Approach: As outlined in the company protocol.

Progress: The results of this study were presented to the American Academy of Orthopaedic Surgery. Efficacy and safety were demonstrated.



# Detail Summary Sheet

Date: 22 Aug 90 Proj No: C-63-88 Status: Completed  
 Title: Long Term Evaluation of the Safety and Efficacy of Topically Applied Capsaicin in Pain Associated with Postherpetic Neuralgia

Start Date 13 Jun 88	Est Comp Date:
Principal Investigator Emil J. Menk, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 9	
Date of Periodic Review 4 Jun 90	Results Completed

Objective(s): This is a long term (up to 12 months), open-label, multi-center clinical trial to evaluate the clinical safety and efficacy of topically applied 0.075% capsaicin cream for the relief of the pain of postherpetic neuralgia.

Technical Approach: Patients who did not gain relief from the blinded short term evaluation were invited to participate in the long term, open-label study to evaluate the efficacy of topically applied 0.075% capsaicin cream. Nine patients were studied.

Progress: Nine patients with postherpetic neuralgia were enrolled in this long term study of topical capsaicin. Three patients continued using the medication for the entire year with one reporting moderate improvement and two reporting slight improvement. Four patients discontinued. Two patients desired to discontinue due to the lack of benefit while the other two discontinued due to concurrent medical problems (one following hospitalization and the other due to memory problems). The other two patients were lost to follow-up.

# Detail Summary Sheet

Date: 19 Jul 90	Proj No: C-66-88	Status: Completed
Title: Lacrimal Pump Quantification		

Start Date 14 Jul 88	Est Comp Date:
Principal Investigator William L. White, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators: A. Tyrone Glover, M.D. Arthur Buckner, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 12	
Total Number of Subjects Enrolled to Date: 12	
Date of Periodic Review 9 Sep 89	Results Continue

Objective(s): To utilize dacryoscintigraphy to quantitate the rate that passage of tears through the lacrimal drainage system is influenced by blinking.

Technical Approach: Subjects were randomized initially to either blink normally or an eyelid-closed dacryoscintigram, with the complementary study being performed after the radiotracer had cleared the lacrimal system. Imaging was done with a 3 mm pinhole collimator and data was acquired for the 0 to 2 minutes (stimulated phase) and 2 to 5 minutes (initial phase) intervals. The tear  $T^{1/2}$  was estimated by finding the slope of the curve plotting the natural logarithm of counts per second against time. The  $T^{1/2}$  in seconds is related to the slope of the following equation:

$$T^{1/2} = 0.693/m$$

where m = slope in seconds<sup>-1</sup>.

Progress: A very rapid appearance of the isotope draining into the lacrimal sac was found. During lid closure examinations however, the greatest decay of tracer occurred during the initial eyelid closure. During one examination, the subject was asked to blink after a five minute non-blinking examination and data was continuously acquired. A dramatic change in the slope of the curve was seen coinciding with the dynamic (blinking) phase of the study.

Conclusions: The data indicate that a significant decrease in tear elimination can be observed during lid closure in the first two minutes following instillation of an eye drop. By extrapolation of the data to topical ocular medications, it

C-66-88 (continued)

appears that a prolongation of drug contact time with the eye is achieved if the eyes are closed immediately. Also the systemic effects of such drugs as timolol, phenylephrine, epinephrine, phospholine iodide, scopolamine, and atropine may be minimized. The data were only found to be statistically significant for the first two minutes following drop instillation. Because of the rapid removal of fluid during the first few blinks after drop placement, it might be anticipated that the best results could be achieved if the eyelids are closed immediately and kept closed for a minimum of two minutes after instillation of an eye drop.

# Detail Summary Sheet

**Date:** 14 Aug 90      **Proj No:** C-76-88      **Status:** Terminated  
**Title:** Double-Blind, Multicenter, Placebo Controlled Clinical Trial to Evaluate the Efficacy and safety of Ha-1A Human Monoclonal Antibody in Patients with Severe Gram-Negative Sepsis/Gram-Negative Septic Shock

<b>Start Date</b> 29 Aug 88	<b>Est Comp Date:</b>
<b>Principal Investigator (vice Ducey)</b> Michael Lamiel, LTC, MC	<b>Facility</b> Brooke Army Medical Center
<b>Dept/Svc</b> Department of Surgery/SICU	<b>Associate Investigators:</b>
<b>Key Words:</b>	David L. Danley, MAJ, MS
<b>Accumulative MEDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> _____	
<b>Total Number of Subjects Enrolled to Date:</b> _____	
<b>Date of Periodic Review</b> 8 Sep 90	<b>Results</b> Completed

**Objective(s):** To determine the efficacy of Ha-1A monoclonal antibody in reducing the mortality and/or direct morbidity of gram-negative sepsis as compared to a placebo group; to determine the impact that Ha-1A has on patient benefit; to determine the impact that HA-1A has on laboratory parameters/clinical signs associated with sepsis; and to determine the safety and potential for immunogenicity of Ha-1A monoclonal antibody administration in patients presenting with the clinical syndrome of gram negative sepsis.

**Technical Approach:** Eligible patients will be randomized to receive either the HA-1A or placebo (human albumin). Therapy will follow the schema outlined in the study protocol.

**Progress:** No patients have been entered into the study since it opened two years ago. The principal investigator has opted to terminate the study.

# Detail Summary Sheet

Date: 14 Aug 90	Proj No: C-77-88	Status: Completed
Title: Storz Intraocular Lens Clinical Trial		

Start Date 29 Aug 88	Est Comp Date:
Principal Investigator Calvin E. Mein, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators: Donald A. Hollsten, LTC, MC Arthur Glover, MAJ, MC
Key Words: Intraocular lens	
Accumulative MUDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 8	
Total Number of Subjects Enrolled to Date: 20	
Date of Periodic Review	Results

Objective(s): To determine postoperative visual acuity of patients receiving an intraocular lens; to measure the occurrence and time course of postoperative ocular complications and adverse reactions for intraocular lens implan subjects; to measure the occurrence of postoperative lens related complications for the intraocular lens implan group; and to measure subgroups within the implant study population that are at "high risk" for the development of particulr complications, as compared to the historical control group.

Technical Approach: As outlined in the company protocol.

Progress: The lens has been approved by the FDA. Therefore, further investigation is unnecessary.

# Detail Summary Sheet

Date: 14 Aug 90 Proj No: C-79-88 Status: Ongoing  
 Title: Collaborative Ocular Melanoma Study

Start Date 8 Sep 88	Est Comp Date:
Principal Investigator Donald A. Hollsten, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators:
Key Words: Melanoma	
Accumulative MEDCASE Cost:	Est Accumulative CMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 8 Sep 90	Results Continue

Objective(s): 1. To determine the efficacy of enucleation versus plaque irradiation in the treatment of medium size ocular melanomas.

2) To determine the efficacy of enucleation without pre-operative external radiation versus enucleation combined with pre-operative external radiation in the treatment of large ocular melanomas.

3) To determine the clinical course and community treatment standards in the treatment of small ocular melanomas.

Technical Approach: As outlined in the Collaborative Group protocol. The principal investigator will serve as the enucleating surgeon on this study.

Progress: No patients from BAMC have been eligible for this study in the last year. This is part of a nationwide study and data collection will continue for another 5-7 years.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-2-89 Status: Ongoing  
 Title: Incidence of Asymptomatic Varicocele in Fertile Men

Start Date 22 Nov 89	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Timothy Dixon, CPT, MC Eric S. Zeidman, MAJ, MC Kurt Hansberry, MAJ, MC Francisco R. Rodriguez, COL, MC
Key Words: Varicocele	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): To determine the incidence of asymptomatic varicocele in a group of men with proven fertility.

Technical Approach: All men requesting bilateral scrotal vas ligations for contraception will be eligible for inclusion. Patient will undergo vasectomy in a routine fashion. Prior to vasectomy, Doppler examination will be performed of the left and right spermatic cords. Patients will be first examined recumbent during comfortable respirations. Then they will be asked to perform a valsalva maneuver, and if a venous whir is detected, will be designated as possessing varicocele by this test. Following venous Doppler, scrotal ultrasound will be performed. If, on valsalva, scrotal ultrasound detects veins within the spermatic cord of 3 mm or greater, a ultrasound-detected varicocele will be scored. Immediately prior to vasectomy, standard semen analysis will be performed to quantitate semen motility, morphology, and total count.

Progress: This study has been placed on an inactive status until Dr. Sabanegh (a urology resident) returns from rotation at Wilford Hall USAF Medical Center.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-6-89 Status: Ongoing  
 Title: Comparison of 2-Suture versus 4-Suture Bladder Neck Suspension in the Treatment of Stress Urinary Incontinence

Start Date 22 Nov 89	Est Comp Date:
Principal Investigator Eric J. Zeidman, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: William Boykin, CPT, MC Ian M. Thompson, MAJ, MC Kurt Hansberry, MAJ, MC Timothy Dixon, CPT, MC Francisco R. Rodriguez, COL, MC
Key Words: Incontinence, stress	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review n/a	Results

Objective(s): To determine the ~~success~~ (as measured by the absence of postoperative incontinence and the presence of normal postoperative micturition) of two different bladder neck suspension techniques in the treatment of stress urinary incontinence associated with hypermobility and malposition of the bladder neck.

Technical Approach: Twenty adult females with objective stress urinary incontinence associated with bladder neck hypermobility and mild cystocele will be randomized into two groups. One group will undergo a traditional 2-suture bladder neck suspension with the two sutures placed at the level of the bladder neck incorporating the medial edge of the endopelvic fascia., pubocervical fascia and vaginal wall minus the epithelium. The second group will undergo a 4-suture bladder suspension with the additional two sutures placed at the level of the bladder base incorporating vaginal wall minus the epithelium, pubocervical fascia and the anterior extension of the cardinal ligaments.

Progress: No complications have been encountered.



# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-7-89 Status: Terminated  
 Title: Comparison of the Effectiveness of Bretylium 5 mg/kg, 10 mg/kg, and 15 mg/kg in the Prevention of Ventricular Fibrillation After Aortic Cross-Clamping

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator Kevin W. Olson, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: William Goglin, MAJ, MC Brent O. Grishkin, COL, MC Charles P. Kingsley, MAJ, MC
Key Words: Fibrillation, ventricular	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To determine the optimal dose of bretylium tosylate to reduce the incidence of ventricular fibrillation after aortic cross-clamp release during myocardial revascularization surgery.

Technical Approach: Thirty adult patients of either sex undergoing elective coronary artery bypass surgery, will be randomized to receive 5 mg/kg, 10 mg/kg, or 15 mg/kg of bretylium tosylate just prior to aortic cross clamp release. Data concerning the frequency of fibrillation, time of its occurrence and requirements for additional antidysthythmic therapy will be compared between groups.

Progress: Project was not begun due to conflicting projects and loss of associate investigators.

# Detail Summary Sheet

Date: 17 Jul 90 Proj No: C-8-89 Status: Completed  
 Title: The Effect of Volume in Tetracaine Spinal Anesthesia

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator Richard B. Hecker, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Charles P. Kingsley, MAJ, MC
Key Words: Anesthesia, spinal tetracaine	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 90	
Total Number of Subjects Enrolled to Date: 90	
Date of Periodic Review 25 Sep 89	Results Continue

Objective(s): To determine if a specific volume of fluid injected into the subarachnoid space, with a fixed dosage of hyperbaric tetracaine based on the patient's height, will affect the average maximal dermatomal spread of anesthesia.

Technical Approach: Ninety adults were randomly assigned to one of three equal groups to receive hyperbaric tetracaine in a volume of 2, 3, or 4 ml. The tetracaine dose was based on the height of the patient. The maximal sensory dermatomal spread following injection was determined by pinprick testing. Our clinical impression has been that larger volumes tend towards a higher dermatomal spread of sensory anesthesia, being most pronounced with 4 ml.

Progress: Two-way analysis of variance (ANOVA) demonstrated no statistically significant difference between volumes of 2 or 3 ml. There was a statistically significant difference between 4 ml and other groups. The addition of epinephrine did not significantly affect spread of anesthesia. We conclude that with hyperbaric tetracaine spinal anesthesia, the use of 2 or 3 ml volume does not affect the spread of anesthesia, but that a 4 ml volume is associated with a significantly greater spread of sensory anesthesia.

# Detail Summary Sheet

Date: 29 Nov 90 Proj No: C-9-89 Status: Ongoing  
 Title: A Comparison of Interpleural Bupivacaine, Epidural Morphine and Systemic Narcotics in Post-Thoracotomy Pain

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator (vice Peterson) Tara I. Chronister, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: William E. Strong, MAJ, MC Charles P. Kingsley, MAJ, MC James E. Newcity, CPT, MC
Key Words: Pain, post-thoracotomy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 29 Jan 90	Results Continue

Objective(s): 1) To compare the effectiveness of interpleural bupivacaine with two commonly utilized methods of pain control.

2) To determine the ease of administration of the interpleural catheter.

3) To provide information as to the benefits of interpleural bupivacaine on postoperative pulmonary function.

Technical Approach: Forty-five patients undergoing thoracotomies will take part in the study, with 15 patients in each group. All patients will undergo pulmonary function testing prior to surgery as well as bedside spirometry post-surgery. A preoperative baseline room air arterial blood gas will be obtained on all patients. Patients will be randomized to one of three groups - Group I, parenteral narcotics; Group II, epidural morphine, Group III interpleural bupivacaine. Patients who do not receive at least 50% reduction in their level of pain within one hour will be considered failures. If either the epidural morphine or the interpleural regional anesthesia techniques are deemed a failure by the attending anesthesiologist, then that technique will be abandoned and parenteral narcotics will be substituted.

Progress: No progress due to change in principal investigators.

# Detail Summary Sheet

Date: 17 Oct 90 Proj No: C-11-89 Status: Terminated  
 Title: Sleep Deprivation, Stress and Vagal Tone

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator Jeffrey Priest, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Charles P. Kingsley, MAJ, MC Donald Fox, CPT, MC Dennis Gilstad, M.D., Ph.D. John A. Dillinger, Ph.D.
Key Words: Sleep deprivation Stress Vagal tone	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 7	
Total Number of Subjects Enrolled to Date: 7	
Date of Periodic Review	Results

Objective(s): To determine the effects of sleep deprivation (two hours or less in a continuous twenty-four hour period of time) and stress on respiratory sinus arrhythmia.

Technical Approach: Individuals who were sleep deprived or engaged in stressful mental and psychomotor activity were studied. Vagal tone as measured by RSA was correlated with salivary cortisol levels, a known predictor of stress. Anesthesia residents provided baseline ECG recordings and salivary samples. Following periods of sleep deprivation, and prior to and after oral presentation, the same parameters were measured. Respiratory sinus arrhythmia (vagal tone) and salivary cortisol levels were examined for correlation of changes due to stress or sleep deprivation.

Progress: The results in the seven individuals studied were too ambiguous to warrant continuation of this study.

# Detail Summary Sheet

Date: 25 Sep 90      Proj No: C-16-89      Status: Ongoing  
 Title: Argon Laser Photocoagulation in the Treatment of Pseudophakic Cystoid Macular Edema

Start Date 20 Dec 88	Est Comp Date:
Principal Investigator Susan L. Parks, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators: Calvin E. Mein, COL, MC
Key Words: Laser, argon photocoagulation Cystoid macular edema	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review 29 Jan 90	Results Continue

Objective(s): To compare observation vs argon laser photocoagulation in the treatment of pseudophakic cystoid macular edema (CMS).

Technical Approach: Fifty patients will be selected who have had CME for greater than six months and have vision worse than 20/40. The patients will be randomly assigned to treatment or observation. Vision, photos, and fluorescein angiograms will be taken on each patient. Both groups will be followed at periodic intervals for up to two years in which vision will be retested and fluorescein angiograms repeated. Improvement in vision in the treatment group will be seen as a positive result favoring the use of laser photocoagulation in aphakic CME.

Progress: Six patients have been enrolled, four were treated and two observed. One observed got better. Of the four treated, two improved significantly.

# Detail Summary Sheet

Date: 17 Jul 90 Proj No: C-18-89 Status: Terminated  
 Title: The Metabolic Effects of Epidural Anesthesia

Start Date 20 Dec 88	Est Comp Date:
Principal Investigator Richard B. Hecker, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Richard D. Culling, MAJ, MC Joseph P. Ducey, MAJ, MC
Key Words: Epidural anesthesia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To compare the metabolic effects of lumbar dural anesthesia (when combined with light general anesthesia) with general anesthesia intraoperatively and during the early postoperative period.

Technical Approach: The subject population will include the ASA physical status classification one through four adult patients who are scheduled for elective abdominal surgery, and who are candidates for placement of a lumbar epidural catheter. This will be a prospective study involving 30 surgical patients. The patients will be randomly assigned to one of two groups. Group one will receive lumbar epidural anesthesia combined with a "light" anesthetic. Group two patients will receive standard inhalational agent plus narcotic anesthesia. The metabolic effects of these anesthetic regimes will be analyzed by indirect calorimetry and serum cortisol determinations.

Progress: Study terminated due to inability to accurately analyze data using indirect calorimetric analysis during the actual delivery of inhalational anesthesia.

# Detail Summary Sheet

Date: 17 Oct 90                      Proj No: C-19-89                      Status: Ongoing  
 Title: Respiratory Sinus Arrhythmia Analysis: A Potential Anesthetic Depth Monitor

Start Date 20 Dec 88	Est Comp Date:
Principal Investigator Eric Lefever, LT, MC, USN	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Charles P. Kingsley, MAJ, MC Don J. Daniels, MAJ, MC Emil Menk, MAJ, MC Dennis Gilstad, M.D., Ph.D., COL, USAFR John A. Dillinger, Ph.D. (Southwest Research Institute)
Key Words: Arrhythmia, respiratory sinus	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 34	
Total Number of Subjects Enrolled to Date: 34	
Date of Periodic Review	Results

Objective(s): To determine whether a correlation exists between depth of general anesthesia and vagal tone as determined by computer analysis of respiratory sinus arrhythmia.

Technical Approach: 70 healthy ASA Class I or II adult volunteers undergoing abdominal surgery will be randomized to receive one of seven standard anesthetic agents: Enflurane, Halothane, and Isoflurane with spontaneous and controlled ventilation will be used. Patients whose ventilation is controlled will receive vecuronium as a muscle relaxant. A final group will receive nitrous oxide and fentanyl in addition to Isoflurane and vecuronium. EKG will be recorded for later analysis of respiratory sinus arrhythmia. Respiratory wave form, blood pressure oxygen saturation, end-tidal CO<sub>2</sub> and inhalational agent concentration will be recorded. The effects of anesthetic agents on respiratory sinus arrhythmia will be analyzed.

Progress: Because of difficulty obtaining data with spontaneously ventilating patients, data is being collected on the four controlled ventilation groups with patients randomized to those four groups as previous. Approximately 90% of the necessary data/patients has been obtained. Technical patterns with the EKG recorder has hampered data collection as well, but should be completed in late October 1990. Data analysis and results can then proceed in a timely manner.

# Detail Summary Sheet

Date: 14 Sep 90	Proj No: C-26-89	Status: Ongoing
Title: Study of Risk Factors in Prostate Disease		

Start Date 27 Jan 89	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Randall E. Harris, Ph.D., M.D. American Health Foundation, New York
Key Words: Prostate disease	Eric J. Zeidman, MAJ, MC Francisco R. Rodriguez, COL, MA
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date: 241	
Date of Periodic Review	Results

Objective(s): To assess various risk factors for the development of prostatic disease.

Technical Approach: This study is designed as a case-control study of patients with carcinoma of the prostate, patients with benign prostatic hyperplasia (BPH), and control patients without evidence of prostatic disease. A questionnaire will be employed to assess risk factors including diet, occupation, medications, activity, smoking, alcohol, sexual history, family history, and voiding pattern. This questionnaire will be administered by a trained epidemiologic interviewer to 100 patients in each group. Additionally several serum steroid and lipid assays will be employed.

Progress: A total of 141 patients with BPH or carcinoma of the prostate and 100 controls are currently enrolled in this study. Fifty nine additional BPH/prostate cancer patients will be enrolled as 100 more controls. Data analysis has not been performed



# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-29-89 Status: Terminated  
 Title: Does BCG Bacteremia Occur After Intravesical BCG Administration?

Start Date 21 Feb 89	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Craig Smith, MAJ, MC Eric Zeidman, MAJ, MC Francisco Rodriguez, COL, MC S. Vern Juchau, COL, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 12 Mar 90	Results _____

Objective(s): To determine if BCG bacteremia occurs frequently following intravesical administration of BCG.

Technical Approach: Patients undergoing BCG instillation will be eligible for this study. Patients will be placed on BCG therapy at the discretion of their primary urologic surgeon. Prior to each instillation, a urinalysis is routinely obtained and, if abnormal, the urine is cultured and the instillation postponed. Ten patients will be studied. Blood cultures will be obtained on treatments 1, 3, and 6.

Progress: In none of the three patients undergoing BCG instillation was BCG bacteremia detected. Due to difficulties with obtaining blood cultures due to a lack of clinic personnel, this study will be closed.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-32-89 Status: Ongoing  
 Title: Effects of Blood Transfusion on the Metabolic Rate as Measured by Indirect Calorimetry

Start Date 21 Feb 89	Est Comp Date:
Principal Investigator James M. Lamiell, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/SICU	Associate Investigators:
Key Words: Calorimetry, indirect	Joseph P. Ducey, MAJ, MC Glen E. Gueller, SFC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To determine the effects of blood transfusion on oxygen utilization in the critically ill patient in various clinical settings and to compare the measurement of oxygen consumption by two different techniques.

Technical Approach: Indirect calorimetry will be performed on each patient using a metabolic measurement cart which involves rapid sampling of inspired and expired gases combined with respiratory gas flow. This will be performed at four different intervals: (1) prior to transfusion, (2) during transfusion, (3) immediately post-transfusion, and (4) 12-24 hours post-transfusion. Metabolic measurements will be made for 12 minutes each time. CBC and SMA-6 will be obtained prior to and post-transfusion.

Progress: Study will continue when staff available.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-35-89 Status: Ongoing  
 Title: Limited Intercarpal Joint Fixation: Techniques and Biomechanical Study  
 Using Cadaver Model

Start Date 21 Feb 89	Est Comp Date:
Principal Investigator (vice Melendez) Ekkard Bonatz, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1,320.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To develop a technique of intercarpal joint fixation using a cadaver model.

Technical Approach: Cadaver specimens consisting of forearm, wrist, and hand will be used. Techniques for fixing the scapho-trapezium-trapezoid joint and the scaphocapitate joints will be studied. The techniques will be divided into those that immobilize the joint through transarticular techniques and those that immobilize the joint through extraarticular techniques.

Progress: Study currently on hold because of impending deployment of principal investigator.

# Detail Summary Sheet

Date: 29 Nov 90 Proj No: C-51-89 Status: Ongoing  
 Title: Evaluation of the Falling Meniscus Sign in Identifying the Epidural Space

Start Date: 3 Apr 89	Est Comp Date:
Principal Investigator (vice Gates) John C. Talbot, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Timothy Castro, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 14 May 90	Results Continue

Objective(s): 1) To evaluate the reliability of the falling meniscus sign in identifying the epidural space.

2) To evaluate the value of the falling meniscus sign as a teaching aid in the instruction of epidural catheter placement by medical personnel.

Technical Approach: This study will consist of 40 patients who will be having epidural catheters placed for anesthetic purposes. Once the skin and interspinous area are anesthetized, the Touhy needle will be placed in the corresponding (1) supraspinous ligament, (2) paraspinal muscle, (3) epidural space identified by the loss of resistance technique and epidural blockade secondary to anesthetic agent given in incremental dosage. In each of these locations a K-53 catheter extension will be connected to the needle and filled with normal saline. The catheter extension will be raised above the level of the needle and observed for a falling meniscus of fluid. Also an epidural catheter will be passed through the needle when it is felt to be in the epidural space and filled with normal saline. The catheter will be raised above the level of the needle and the hump of the catheter observed for a falling meniscus of fluid. If the meniscus falls freely, the test will be interpreted as positive.

Progress: None due to change in principal investigators.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-52-89 Status: Ongoing  
 Title: A Prospective, Randomized Study of Balloon Dilatation vs. Transurethral Resection of the Prostate for Benign Prostatic Hyperplasia

Start Date: 3 Apr 89	Est Comp Date:
Principal Investigator Eric J. Zeidman, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 6,094.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 14 May 90	Results Continue

Objective(s): To determine the relative benefits of balloon dilatation vs TURP for BPH.

Technical Approach: A total of 40 patients will be enrolled in the study. Patients will be randomized into two arms: Arm I - standard TURP, Arm II - balloon dilatation. Patients will undergo preoperative urodynamic evaluation with pressure flow studies. A Questionnaire concerning sexual history and urinary symptoms will be administered. Patients will be seen two weeks following their procedure at which time uroflowmetry is performed. Patients are then followed on an every 3 month basis for one year. At 3, 6 and 12 months of follow-up, complete pressure-flow urodynamic measurement is performed. Efficacy of the two treatment modalities will be compared as follows: 1) symptom score, 2) uroflowmetry, 3) treatment failures, treatment side effects, and repeat procedures.

Progress: No reportable data are available at this time.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-53-89 Status: Continue  
 Title: A Comparison of Arterial Oxygen Partial Pressures Achieved with Intermittent Flow Oxygen (IF) from a Demand Oxygen Controller and Continuous Flow Oxygen (CF)

Start Date: 3 Apr 89	Est Comp Date:
Principal Investigator Charles P. Kingsley, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Joseph P. Ducey, MAJ, MC William Strong, CPT, MC Linda Strezlecki, LTC, AN
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 15	
Total Number of Subjects Enrolled to Date: 15	
Date of Periodic Review 11 May 90	Results

Objective(s): Animal studies and human studies in chronically ill patients have shown that intermittent flow oxygen delivered by a demand oxygen controller (DOC) maintains arterial oxygen tensions at values that are equal to those values with continuous flow oxygen (CF). Twenty five postoperative patients for pulmonary surgery will be studied in a randomized crossover design.

Technical Approach: Twenty five adult patients scheduled for pulmonary surgery requiring routine arterial catheter placement and postoperative intensive care admission will be enrolled in the study. A randomized crossover design with each patient serving as his own control will be employed to evaluate the arterial oxygen partial pressures achieved with intermittent oxygen therapy from a demand oxygen controller compared to continuous flow oxygen at comparable flow rates. Arterial blood gases will be drawn at 30 minute intervals, and total oxygen use will be recorded. Continuous pulse oximetry will insure adequate oxygen delivery.

Progress: Preliminary data are being analyzed.

# Detail Summary Sheet

Date: 14 Sep 89 Proj No: C-65-89 Status: Completed  
 Title: Review of Keller Bunionectomy Procedures

Start Date: 5 May 89	Est Comp Date:
Principal Investigator Harlan Stratton, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Henry Chambers, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine if the Keller bunionectomy procedure is successful in relieving forefootpain, improving cosmesis, allowing use of normal footwear, and to what degree it is able to improve the overall function in patients with the hallux valgus deformity.

2) To define the failure rates and mode of failure of the Keller bunionectomy.

3) To determine if the continued clinical usage of the Keller bunionectomy is indicated based on subjective and objective data collected from patients on whom this procedure has been performed.

Technical Approach: The last 100 consecutive adult patients who have had a Keller procedure at BAMC will be evaluated. A patient questionnaire will allow subjective, i.e. patient, evaluation of the surgical results. Objectively the patient will be examined for cosmesis, mobility and pin in the interphalangeal joint, pain or stiffness with metatarsalphalangeal joint motion, residual inflammation on medial metatarsal, residual hallux valgus deformity, pronation of the hallux, plantar callosities of the lesser metatarsals, and pressure distribution under the foot by use of the Harris foot mat.

Progress: Results of this study were reported for fulfillment of residency requirement. However, a copy was not furnished to the Department of Clinical Investigation.

# Detail Summary Sheet

Date: 20 Sep 90 Proj No: C-66-89 Status: Completed  
 Title: Evaluation of the Effect of Postoperative Wound Drainage Reinfusion Using the Solcotrans Orthopaedic Drainage/Reinfusion System in Reducing the Need for Whole Blood Transfusion.

Start Date: 5 May 89	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Michael B. Simpson, MAJ, MC Henry G. Chambers, MAJ, MC Kevin P. Murphy, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$4,768.00 (R&D Funds)
Number of Subjects Enrolled During Reporting Period: 24	
Total Number of Subjects Enrolled to Date: 24	
Date of Periodic Review 11 May 90	Results Continue

Objective(s): To evaluate the efficacy of reinfusion of postoperative wound drainage in decreasing the need for whole blood transfusion in patients with significant sanguineous postoperative drainage.

Technical Approach: Twenty four consecutive patients undergoing elective primary total joint arthroplasty were randomized to one of two groups. The control group consisted of twelve patients (9 TKA's, 3 THA's) in whom a standard spring-loaded intermittent suction system was used postoperatively. The study group consisted of twelve patients (9 TKA's, 3 THA's) in whom the Solcotrans Orthopaedic Wound Drainage/Reinfusion device was utilized to reinfuse postoperative blood losses. Patients were transfused for hematocrits below thirty.

Progress: Postoperative blood loss averaged 1087 cc in the study group compared to 551 cc in the control group. Ten of the twelve control patients (83.3%) required postoperative transfusions. Despite greater blood losses, only three of study patients (25.0%) required transfusions. Only one of the nine TKA's (11.1%) in the study group required transfusion, compared to seven of nine (77.7%) of the control TKA's. The increased incidence of postoperative transfusions in the control group was statistically significant ( $P < 0.01$ ). The average hematocrit of the reinfused wound drainage was 32.7. There were no complications related to the use of the device and all cultures were sterile. No evidence of coagulopathy was seen in the study group.



C-66-89 (continued)

Conclusions: The collection of postoperative wound drainage and subsequent reinfusion using the Solcotrans device is a safe, effective means of decreasing the postoperative transfusion requirements in elective total joint arthroplasty. The effect appears more dramatic in patients undergoing total knee arthroplasty than in total hip arthroplasty. The unit also results in higher postoperative blood loss, which may either be due to increased postoperative bleeding from the constant suction or to more effective wound evacuation than standard intermittent suction drainage systems.

# Detail Summary Sheet

Date: 30 Jun 90	Proj No: C-76-89	Status: Terminated
Title: Thyro-Glossal Duct Cyst (TGDC)		

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator (vice Hayes) David K. Hayes, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators: Jesse Moss, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To characterize the presentation of true thyroglossal duct cyst that may aid in establishing the diagnoses.

Technical Approach: All inpatient medical records of patients with an admission or discharge diagnosis or operative diagnosis of TGDC will be reviewed. Attempts will be mde to contact all subjects who underwent a surgical procedure to obtain current information on their postoperative course and recurrence of the cyst.

Progress: This study was terminated due to transfer of the principal investigator and no interest in pursuing the study by other assigned personnel.

# Detail Summary Sheet

Date: 26 Sep 90 Proj No: C-78-89 Status: Completed  
 Title: Respiratory Sinus Arrhythmia Analysis During Spinal Anesthesia Evaluation of Vagal Tone in Relation to Anesthetic Levels

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Jeff Baeuerle, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 34	
Total Number of Subjects Enrolled to Date: 34	
Date of Periodic Review 14 May 90 Results Continue	

Objective(s): To investigate the relationship between vagal tone (as determined by computerized respiratory sinus arrhythmia analysis) and dermatomal level of spinal anesthesia.

Technical Approach: The electrocardiogram of adult patients undergoing surgical procedures with spinal anesthesia will be recorded on magnetic tape for computer analysis of R-R interval variation. This beat to beat variability may be altered in patients with spinal anesthesia as a result of altered autonomic tone. Patient care and management will not be altered in any way. Computer analysis of the taped ECG signal will be performed at Southwest Research Institute.

Progress: Thirty-four patients were studied. Eight patients received hyperbaric lidocaine, while thirteen patients had hyperbaric bupivacaine and thirteen had hyperbaric tetracaine. The mean vagal time (VT) prior to placement of SAB was 4.7 and the mean VT at highest anesthetic level was 4.8. Five lidocaine patients had an increase in VT while three patients had a decrease. An equal number of bupivacaine patients (6 each) had an increase or decrease in VT, while 1 patients had no change. Eight tetracaine patients had an increase in VT while four patients had a decrease and one patient had no change. There was no correlation between levels of analgesia or occurrence of hypotension, and changes in VT from baseline. The direction of VT changes was not predictive. Vagal tone, as determined by respiratory sinus arrhythmia analysis, does not appear to change significantly with sensory levels during subarachnoid block.

# Detail Summary Sheet

Date: 17 Oct 90 Proj No: C-79-89 Status: Ongoing  
 Title: Comparison of Equipotent Doses of Bupivacaine and Tetracaine in Spinal Anesthesia

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Don J. Daniels, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 May 90	Results Continue

Objective(s): To compare the adequacy and duration of equipotent doses of bupivacaine and tetracaine in pregnant females requesting spinal anesthesia for cesarean section.

Technical Approach: One hundred healthy parturients will be studied in a randomized, double blind fashion. After prehydration, 10 mg of either tetracaine or bupivacaine in 7.5% dextrose will be placed subarachnoid at the L3-L4 level via a 25 gauge spinal needle. The onset will be evaluated by loss of cold sensation at the distribution of the lateral cutaneous nerve. Sensory function will be tested at two minute intervals by pinching the skin with Allis forceps until the sensory level is seen to stabilize. Motor blockade will also be assessed.

Progress: Elective C-sections are almost nonexistent due to changed criteria. Thus far we have been unable to obtain volunteers from the group of patients who have failed to progress.

# Detail Summary Sheet

Date: 11 May 90 Proj No: C-80-89 Status: Terminated  
 Title: Treatment of Refractory Ulcers in Epidermolysis Bullosa Using Cultured Epidermal Allografts

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Jesse Moss, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators:
Key Words: Epidermolysis bullosa	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 14 May 1990	Results Terminate

Objective(s): To isolate and grow epidermal allografts from cells obtained from a skin biopsy performed on the parent of a child with junctional epidermolysis bullosa.

Technical Approach: A small piece of skin will be obtained from the upper buttock area. The cells thus obtained will be planted on plastic tissue culture plates containing Keratinocyte Growth Medium (KGM) which has recently been developed for the growth of keratinocytes. Attempts will be made to manipulate the media to induce the growth of multilayer epidermal sheets which will be transplanted onto nonhealing eroded areas on the child with junctional epidermolysis bullosa.

Progress: This is a single patient protocol. Since the retirement of the principal investigator, LTC Moss, the mother has opted to continue therapy of the child at Wilford Hall USAF Medical Center.

# Detail Summary Sheet

Date: 14 Aug 90 Proj No: C-86-89 Status: Completed  
 Title: The Effects of Topical-Oral Clindamycin Antibiotic Rinses on Bacterial Content of Saliva in Healthy Human Subjects

Start Date: 10 Jul 89	Est Comp. Date:
Principal Investigator E. Scott Elledge, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators: Kweon I. Stambaugh, LTC, MC Robert G. Whiddon, Jr., LTC, MS Eleanor F. Ayala, MT Sheila K. Jones, SSG
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 20	
Total Number of Subjects Enrolled to Date: 20	
Date of Periodic Review 8 Sep 90	Results Completed

Objective(s): To compare the bacterial contents of oral cavity saliva in healthy human adult subjects before and after using an oral rinse containing the antibiotic clindamycin versus a control rinse of normal saline.

Technical Approach: Twenty adult males and females, who had been without systemic antibiotics during the two weeks prior to the study were enrolled. An initial saliva sample was obtained by having the subjects rinse their mouths with 30 cc of normal saline and expectorate the rinse into a sterile specimen container. The sample was plated on trypticase soy agar (TSA) with 5% sheep blood agar for aerobic culture. From this same sample an equivalent amount was placed into a Gas Pak for anaerobic culture. This initial sample served as a baseline for subsequent counts. After 30 minutes, each subject was given 30 cc. of sterile normal saline as an oral rinse for a total of ten seconds. The saline was expectorated and discarded. The subjects were divided randomly into two groups of ten each. Ten of the subjects were given 30 cc of clindamycin mouthwash solution prepared by dissolving the contents of a 150 mg capsule in 250 cc of sterile normal saline. The second group of ten subjects used another 30 cc of normal saline as previously described. The expectorate from both groups was discarded. Additional saliva samples from both groups were taken one and four hours later in the same manner as the first sample.

The aerobic and anaerobic cultures were incubated for 24 and 48 hours, respectively, and all colonies counted. The number of viable bacteria per milliliter was calculated by multiplying the number of colonies by the reciprocal of the dilution.

C-86-89 (continued)

Progress: The data show that at  $p < 0.05$  for both aerobes and anaerobes there was a significant reduction in bacterial colony counts at both one and four hours post-treatment in the clindamycin group. For the group that rinsed with saline placebo, there was no significant difference at one and four hours. There was no significant difference in the anaerobic background colony counts or in the aerobic background colony counts between the two groups. There was a wide range of background counts within each group. Anaerobes ranged from  $10 \times 10^4$  to  $333 \times 10^4$ , and aerobes ranged from  $3 \times 10^4$  to  $308 \times 10^4$  colony forming units per milliliter.

Conclusion: Oral rinses with clindamycin can reduce the bacterial content of saliva for a sufficient length of time to be effective as a preoperative prophylactic measure for head and neck surgery involving the upper aerodigestive tract. Future studies are planned to evaluate other potentially effective agents.

# Detail Summary Sheet

Date: 2 Jan 90 Proj No: C-87-89 Status: Terminated  
 Title: Lung Cancer Study Group Protocol NC3: Registry of Patients with T<sub>1</sub>N<sub>1</sub> Disease Only.

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator (vice Grishkin) James A. Ameika, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators: Greg Bowman, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To maintain a registry of patients with T<sub>1</sub>N<sub>1</sub> Disease only.

Technical Approach: All patients who are found to be T<sub>1</sub>N<sub>1</sub> staged clinically and surgically will be potential candidates if patient eligibility criteria are met.

Progress: Effective 1 January 1990, all Lung Cancer Study Group protocols were terminated.



# Detail Summary Sheet

Date: 22 Aug 90 Proj No: C-94-89 Status: Ongoing  
 Title: Use of Intravenous Ismelin® in Patients with Reflex Sympathetic Dystrophy, Causalgia, or Raynaud's Phenomenon/Disease

Start Date: 16 Jul 89	Est Comp Date:
Principal Investigator William Strong, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Emil Menk, MAJ, MC Donald Daniels, MAJ, MC Roger Wesley, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 9	
Total Number of Subjects Enrolled to Date: 9	
Date of Periodic Review	Results

Objective(s): To provide guanethidine monosulfate on a compassionate use basis and review the safety of sympathetic blockade caused by the intravenous administration of guanethidine monosulfate in an isolated limb affected by reflex sympathetic dystrophy (RSD), causalgia, or Raynaud's phenomenon/disease.

Technical Approach: Patients meeting the criteria for inclusion in the study will undergo complete history and physical examination, electrocardiogram, laboratory evaluations and urinalysis. Bier Block with Ismelin® IV and lidocaine 0.5% will be accomplished. The number and frequency of the treatments will be determined on an individual basis. One month later patients will be asked to return for follow-up evaluation.

Progress: This is a multiinstitutional study to determine safety of this drug for use on a routine basis. To date, only mild side effects (i.e. localized pruritis, mild orthostatic hypotension treated with intravenous fluids) have been noted which were reported to the drug company (Ciba-Geigy). Seven of the nine patients studied had complete or near complete resolution of their pain.

# Detail Summary Sheet

Date: 22 Aug 90 Proj No: C-95-89 Status: Ongoing  
 Title: Effect of the Use of Perioperative Antibiotics on the Incidence of Wound Infection Following Mastectomy

Start Date: 1 Aug 89	Est Comp Date:
Principal Investigator Steven B. Olsen, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/General Surgery	Associate Investigators: Daniel P. Otchy, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 28	
Total Number of Subjects Enrolled to Date: 28	
Date of Periodic Review	Results

Objective(s): To prospectively analyze the effect of perioperative antibiotic use on the incidence of wound infection following mastectomy.

Technical Approach: The subject population will include all females who present to the General Surgery Service from August 1989 to December 1990. The subjects will be randomized to one of two double-blinded groups; the first group will receive intravenous antibiotics in a standard perioperative regimen consisting of a dose preoperatively and postoperative doses for 24 hours postoperatively, and the second group will receive intravenous doses of saline at the same times when antibiotics would normally be administered. The incidence of wound infections and other infective complications will be monitored during the hospital stay and at follow-up visits.

Progress: Twenty-eight patients have been entered into the study. No complications or adverse reactions have been encountered to date. A total of approximately 105 patients will be needed to ensure statistical significance.

# Detail Summary Sheet

Date: 29 Nov 90 Proj No: C-97-89 Status: Ongoing  
 Title: I.V. Fluid Administration and the Occurrence of Urinary Retention  
 (Spinal and General Anesthesia)

Start Date: 1 Aug 89	Est Comp Date:
Principal Investigator (vice Hartman) Douglas J. Loughhead, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Timothy Castro, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 12 Sep 90	Results Continue

Objective(s): To determine if the amount of intravenous fluids a patient receives peri-operatively has an effect on the incidence of urinary retention.

Technical Approach: Patients meeting the inclusion criteria will be randomized to one of two groups. Prior to institution of anesthesia, patients will receive either one-fourth (Group A) or one-half (Group B) of their calculated fluid deficit, then placed on their calculate maintenance infusion for the remainder of the anesthetic. The incidence of urinary retention as based on (1) the urge to but inability to urinate or (2) a volume of more than 400 cc obtained from in and out catheterization 3-4 hours postoperatively, will be determined postoperatively.

Progress: None due to change in principal investigators.

# Detail Summary Sheet

Date: 25 Sep 90 Proj No: C-99-89 Status: Terminated  
 Title: Hyperbaric Oxygen Therapy in the Treatment of Non-Healing Diabetic Lower  
 Extremity Lesions. (Collaborative Study with Hyperbaric Medicine Division,  
 School of Aerospace Medicine, Brooks AFB)

Start Date: 1 Aug 89	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Robert M. Ingle, Jr., COL, USAF MC
Key Words:	
Accumulative MEDCASF Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 25 Sep 90 Results Terminated	

Objective(s): To investigate the role of intermittent hyperbaric oxygenation in  
 diabetic wound healing.

Technical Approach: All patients will receive the best standard of conventional  
 care. Meticulous debridement of wounds will be done whenever indicated, and  
 wound care will be standardized as much as possible. Patients will be ran-  
 domized into the oxygen group (90 minutes of 100% oxygen at 2.4 atmospheres  
 absolute [ATA] daily) or the control group (90 minutes of 8.75% oxygen at 2.4  
 ATA daily, which is equivalent to breathing air at sea level). Patients will  
 undergo 20-40 treatments in the hyperbaric chamber. If a major surgical proce-  
 dure is planned, 5-10 treatments will be given preoperatively if possible.

Progress: Failure to achieve enrollment of patients is secondary to absence of  
 interservice coordination and cooperation. Patients requiring Hyperbaric Oxygen  
 therapy continue to receive treatment, but have not been involved with a  
 prospective study, as the principal investigator for the USAF is no longer  
 assigned. Termination is recommended.

# Detail Summary Sheet

Date: 27 Aug 90 Proj No: C-100-89 Status: Completed  
 Title: Pilot Study of Quality of Life Questionnaire of Prostatic Disease

Start Date: 1 Aug 89	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the ease of use of the prostate-specific Quality of Life (QOL) questionnaire and to identify any internal inconsistencies or difficulties with patient understanding of the questionnaire.

Technical Approach: Ten adult males with diagnosed diseases of the prostate will complete the QOL questionnaire. An administration checklist will be completed. Final data, including only patient identification number and disease process will be forwarded to Dr. Moinpour at the Fred Hutchinson Cancer Research Center in Seattle for analysis.

Progress: A total of 7 patients were entered on study. All patients completed the questionnaire and results were compiles. No further patients will be entered as data acquired with 7 has been acceptable. Results of the study will probably be reported in a subsequent publication.

# Detail Summary Sheet

Date: 25 Sep 90 Proj No: C-101-89 Status: Terminated  
 Title: Hyperbaric Oxygen Therapy as an Adjuvant in the Treatment of Chronic Refractory Osteomyelitis. (Collaborative Study with Hyperbaric Medicine Division, School of Aerospace Medicine, Brooks AFB)

Start Date: 1 Aug 89	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: Robert M. Ingle, Jr., COL, USAF MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 25 Sep 90	Results Terminate

Objective(s): To determine and document in a controlled fashion the effectiveness of hyperbaric oxygen (HBO) therapy in the adjuvant treatment of chronic refractory osteomyelitis (CROM).

Technical Approach: All patients will receive the best standard of conventional care. Baseline data to be collected: CBC and platelet count; ESR (beginning and end); bone biopsy through non-infected tissue and bone culture; magnified views and tomograms if needed; bone scan, Gallium scan and CT scan. Patients will be randomized into the oxygen group (90 minutes of 100% oxygen at 2.4 atmospheres absolute [ATA] daily) or the control group (90 minutes of 8.75% oxygen at 2.4 ATA daily, which is equivalent to breathing air at sea level). Patients will undergo 10-20 treatments followed by a further surgical procedure designed to permanently eradicate the infection, excluding amputation. Intravenous antibiotics will be administered for 4-6 weeks after appropriate culture and sensitivity reports. Postoperatively, hyperbaric treatments will be given for a total of 40-60 treatments before and after surgery.

Progress: Failure to achieve enrollment of patients is secondary to absence of inter-service coordination and cooperation. Patients requiring Hyperbaric Oxygen Therapy continue to receive treatment, but have not been involved with a prospective study, as the principal investigator for the USAF is no longer assigned. Termination is recommended.

# Detail Summary Sheet

Date: 14 Aug 90      Proj No: C-115-89      Status: Ongoing  
 Title: Treatment of Metastatic Renal Cell Carcinoma with Cimetidine: A Phase II Trial

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator MAJ Ian M. Thompson	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Arlene J. Zaloznik, LTC, MC M. Ernest Marshall, M.D.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review	Results

Objective(s): 1) To evaluate the likelihood of response in order to assess whether this regimen should be advanced to further studies.

2) To evaluate qualitative and quantitative toxicities of this regimen administered in a phase II study.

Technical Approach: All patients will receive cimetidine, 400 mg orally four times daily. There will be no dose reduction or escalation within this trial. Patients experiencing significant CNS toxicity will be removed from study. Any other toxicities requiring cessation of therapy will be documented.

Progress: Thus far, two patients are on-study. One patient has extensive renal cell carcinoma with several pulmonary metastases. At six month follow-up he has exhibited no untoward side effects of the medication and continues to have an excellent performance status. None of his metastatic lesions have exhibited a response but none have increased in size. The second patient was hospitalized at BAMC for gastric outlet obstruction and biliary obstruction secondary to the renal cell carcinoma. An exploratory laparotomy found the disease to be unresectable and gastrostomy and feeding jejunostomy were performed. A follow-up letter was sent to his attending physician at Fort Leonard Wood but no response has been received.

# Detail Summary Sheet

Date: 6 Sep 90                      Proj No: C-116-89                      Status: Ongoing  
 Title: Evaluation of the Effect of Postoperative Wound Drainage Reinfusion  
 Using the Solcotrans Orthopaedic Drainage/Reinfusion System in Reducing the Need  
 for Whole Blood Transfusion in Spinal Fusion Patients

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator Jeffrey D. Coe, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Michael B. Simpson, CPT, MC Allan L. Bucknell, COL, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$4000.00
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 10 Sep 90	Results Ongoing

Objective(s): To evaluate the efficacy of reinfusion of postoperative wound drainage in increasing the need for whole blood transfusion in spinal fusion patients with significant sanguineous postoperative drainage.

Technical Approach: Wound drainage will be collected for a total of six hours. At the end of that time the amount of drainage will be noted. If greater than 350 ml are present, the system will be configured for reinfusion and a new collection unit will be connected to the drainage tube(s) in a sterile fashion and again placed under constant suction. For collection volumes from 150-350 ml the system will be configured for reinfusion and a standard Hemovac suction container will be attached to the drainage tubes. Amounts less than 150 ml will not be reinfused. An aliquot of blood will be collected from each Solcotrans unit configured for reinfusion and submitted for CBC, aerobic and anaerobic cultures.

Progress: Two patients were found to have positive blood cultures after reinfusion. However, there were no clinical infections. This study will be suspended until data are available on the possible sources of the positive cultures.



# Detail Summary Sheet

Date: 17 Jul 90 Proj No: C-117-89 Status: Completed  
 Title: Pitfalls of Spinous Process Wiring in the Cervical Spine

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator Jeffrey D. Coe, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Michael B. Simpson, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): To study the safety of a presumably "fail-safe" method for internal fixation of the cervical spine used in posterior cervical spinal fusions for various indications including trauma, degenerative disorders, reconstructive situations, and inflammatory disorders that result in cervical instability.

Technical Approach: Three intact cervical spines were harvested from preserved cadavers, from the first cervical to the seventh cervical vertebra. Paraspinal muscles were removed from all specimens using sharp dissection. The ligamentous structures were left intact, and the specimens remained fully articulated. Anteroposterior and lateral radiographs were obtained of all three specimens to verify the absence of radiographic pathology. Trans-spinous wires were then passed through each spinous process from C2 to C7 for each of the specimens. The trans-spinous holes created for the wire passages were made using a different technique for each specimen. In specimen 1, the holes were created close to the base of the spinous process with the use of a sharp towel clamp. In specimen 2, a high speed burr with a right angle attachment was used to create the holes. In specimen 3, the holes were also created with a towel clp, but were placed more posteriorly than those in the first specimen. Trans-spinous wires were then passed through each specimen. A lateral radiograph was obtained of each specimen, and attention directed to which wires appeared to have violated the spinal canal and were anterior to the spinolaminar line. The specimens were then disarticulated, and each vertebral segment was closely inspected for evidence of canal violation.

C-117-89 (continued)

Progress: Lateral radiographs of the fully articulated specimens were reviewed. In specimen 1, four of the six wires were noted to be anterior to the spinolaminar line at C3, C4, C5, and C6. The relatively long spinous processes at C2 and C7 seemed to help prevent inadvertent canal violation with wire passage. In specimen 2, only a single wire of the six was noted to be anterior to the spinolaminar line at C5. The wire at C6 was right at the spinolaminar line, but did not appear to violate the spinal canal. In specimen 3, no wire was noted to be anterior to the spinolaminar line.

Upon disarticulation, the vertebral segments from each specimen were reviewed and radiographs obtained. In specimen 1, disarticulation proved that the wires at C3, C4, C5, and C6 had all indeed violated the spinal canal. At C4, the wire had lacerated the dura. At C3, C4, and C5 the wire appeared to be sufficiently anterior to have impinged on the dorsal aspect of the spinal cord during wire passage. At C6, there appeared to be sufficient space available for the cord.

In specimen 2, two wires violated the spinal canal. Neither of the two wires appeared to be impinging on the spinal cord remnant at that level.

None of the wires in specimen 3 violated the spinal canal. The wire at C4, which had appeared suspiciously close to the spinolaminar line on the lateral radiograph, had not violated the canal.

When the findings in the disarticulated specimens were compared to the findings on the lateral radiographs, it was evident that the spinolaminar line was a valid radiographic landmark for the posterior aspect of the spinal canal.

Conclusions: The risk of potential neurologic compromise, as a result of wires violating the spinal canal, can be minimized by:

1. Careful preoperative radiographic analysis;
2. A formal knowledge of the varying anatomic relationships within the cervical spine, which allows for proper hole placement; and
3. Intraoperative assessment of any difficult wire passage, including radiographic evaluation.

# Detail Summary Sheet

Date: 29 Nov 90 Proj No: C-119-89 Status: Ongoing  
 Title: Shoulder Impingement Syndrome: Response to Conservative Treatment and the Predictive Value of Some Associated Clinical and Radiographic Findings

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator Michael B. Simpson, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Dale C. Young, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 12 Sep 90 Results Continue	

Objective(s): To prospectively study the response of shoulder impingement syndrome to conservative and operative treatments currently utilized at Brooke Army Medical Center

Technical Approach: History, physical examination, radiographs of the involved shoulder and cervical spine, and an impingement test will be obtained at the initial visit. Conservative therapy will be initiated to include a Physical Therapy, a program of home therapy and, a non-steroidal anti-inflammatory agent (NSAIA). The patient would next be seen approximately six weeks following the initial evaluation. At that time a repeat history and physical examination would be done. Patients who are responding well to conservative treatment would be continued on that program. Those who fail to respond will then receive a single injection of Dexamethasone mixed with Xylocaine into the involved subacromial bursa. Patients who either continue to have severe symptoms after three months of conservative therapy, who demonstrate a loss in motion, or who have persistent severe functional impairment will be offered surgical intervention.

Progress: None due to the principal investigator's six month rotation at Fitzsimons Army Medical Center.

# Detail Summary Sheet

Date: 6 Sep 90 Proj No: C-127-89 Status: Ongoing  
 Title: A Randomized Prospective Study of Lumbar Spinal Fusions with and without Transpedicular Screw-Plate Fixation

Start Date: 31 Oct 89	Est Comp Date:
Principal Investigator Jeffrey D. Coe, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: William C. Lauerman, MAJ, USAF MC James E. Cain, MAJ, USAF MC Kevin P. Murphy, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 12	
Total Number of Subjects Enrolled to Date: 12	
Date of Periodic Review 10 Sep 90	Results Continue

Objective(s): To compare the results of spinal fusion with and without the use of transpedicular instrumentation in the lumbar spine.

Technical Approach: In a multi-center study to be performed by the Orthopaedic Surgery Services of the Joint Military Medical Commander of San Antonio, a randomized prospective study will be performed in patients undergoing lumbar spinal fusions. The study group will undergo transpedicular instrumentation with Steffee (VSP) bone plates and screws and the control group will undergo fusion without instrumentation. A total of 100 patients will be entered into the study (approximately 30 to 40 at BAMC). The primary goal of the study is to determine if there is a difference in subjective pain relief, fusion rates, and complication rates between the study group (instrumented and fused) and the control group (uninstrumented and fused).

Progress: There have been no untoward effects in the experimental group that necessitate reconsideration of the study goals. Data accumulation is progressing well. At this time there is insufficient data to report any significant conclusions.

# Detail Summary Sheet

Date: 20 Sep 90 Proj No: C-8-90 Status: Ongoing  
 Title: Clinical Evaluation of Collagen/Chlorhexidine (VitaPatch) Surgical Dressing and Traction Pin Bandage

Start Date 7 Dec 89	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: Daryl W. Peterson, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): To evaluate the safety and effectiveness of a new pin protection device called VitaPatch™. The effectiveness of VitaPatch will be evaluated in terms of differences in the rate of bacterial colonization/infection, site appearance, convenience of use, and patient comfort as compared with established protocol.

Technical Approach: All patients over the age of 18 who have fresh fractures treated with external fixation devices will be eligible for the study. Prospective patients are evaluated at the request of the primary physician, and a determination for inclusion made by the primary investigators. Each patient will serve as his/her own control with the same number of pins used as controls as the number of pins testing VitaPatch. Control VitaPatch test pins are to be alternated so that no bias is introduced.

Progress: Thus far, safety and efficacy in over 50 pin sites demonstrated. No pin sites with chlorhexidine have become infected.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-17-90 Status: Ongoing  
 Title: Quality of Life in Patients Undergoing Hormonal Manipulation for Carcinoma of the Prostate.

Start Date 18 Jan 90	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Urology Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review	Results

Objective(s): To determine in what manner and to what extent, hormonal manipulation effects the quality of life of patients with metastatic or advanced carcinoma of the prostate.

Technical Approach: Using an NCI-approved Quality of Life instrument, this study will pilot the question of how and to what degree Quality of Life is affected by hormonal stimulation in patients with prostate carcinoma.

Progress: This study is now competing with a SWOG study of QOL in patients with D2 carcinoma of the prostate.

# Detail Summary Sheet

Date: 28 Sep 90 Proj No: C-18-90 Status: Ongoing  
 Title: A Randomized Prospective Clinical Trial of Vitrectomy in the Management of Idiopathic Macular Holes.

Start Date 18 Jan 90	Est Comp Date:
Principal Investigator Dwight W. Wood, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators: Calvin E. Mein, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 8	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review	Results

Objective(s): The goal of this study is to determine if core vitrectomy with posterior hyaloid membrane peeling and gas fluid exchange is of benefit in restoring visual loss due to macular hole.

Technical Approach: Comparison of the rates of visual recovery, macular hole resolution, and operative complications occurring prospectively in 40 patients with idiopathic macular holes who are randomized to 1) an untreated control group or 2) a study group undergoing vitrectomy will be made.

Progress: To date, no significant improvement has been evidenced in four eyes undergoing PPV as compared to six control eyes in our eight patients. Our limited trial does not support the previously reported prediction that 50% of patients would experience some measurable improvement in vision. No serious complications resulting from PPV have been noted in our cohort. The study will continue as previously described.

# Detail Summary Sheet

Date: 27 Sep 90 Proj No: C-19-90 Status: Ongoing  
 Title: Effect of Mini-dose Fentanyl on Subarachnoid Anesthesia with Isobaric Lidocaine.

Start Date 18 Jan 90	Est Comp Date:
Principal Investigator Douglas Chapman, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: R.K. Baumgarten, LTC, MC K. Kenworthy, CPT, MC
Key Words: Subarachnoid block Fentanyl Narcotic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 29	
Total Number of Subjects Enrolled to Date: 29	
Date of Periodic Review	Results

Objective(s): The purpose of this randomized, double-blind study is to determine if the addition of mini-dose fentanyl (10 mcg) improves the quality of spinal anesthesia produced by isobaric lidocaine (80 mg).

Technical Approach: Patients who request spinal anesthesia for lower extremity orthopaedic procedures and lower abdominal surgery will be eligible for this study. A total of 100 patients will be studied (control + treatment groups). All blocks will be placed in the sitting position utilizing a midline approach at L3-4 with a #25 needle. The control group will receive 4 ml of 2% lidocaine plus 0.2 ml normal saline. The treatment group will receive 4 ml of 2% lidocaine plus 0.2 ml fentanyl. Quality of analgesia will be assessed using the following parameters: 2) level of pinprick at 10, 20, 30 and 60 minutes, 2) patient complains of pain on incision or tourniquet pain, 3) dosage of supplementary analgesics intraoperatively and in the recovery room. Occurrence of nausea, vomiting or pruritus will be recorded.

Progress: We are still collecting data and compiling cases but at this point are unable to draw any conclusions. No complications have occurred as a consequence of this study. No new risks have been identified. The study is continuing as designed without change.



# Detail Summary Sheet

Date: 25 Sep 90 Proj No: C-20-90 Status: Ongoing  
 Title: Effect of Mini-dose Fentanyl on Subarachnoid Anesthesia with Isobaric Bupivacaine.

Start Date 18 Jan 90	Est Comp Date:
Principal Investigator Kevin Kenworthy, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Dept of Surgery Anesthesia and Operative Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 20	
Total Number of Subjects Enrolled to Date: 20	
Date of Periodic Review	Results

Objective(s): The purpose of this randomized, double-blind study is to determine if the addition of mini-dose fentanyl (10 mcg) improves the quality of spinal anesthesia produced by isobaric bupivacaine (20 mg).

Technical Approach: Patients who request spinal anesthesia for lower extremity orthopaedic procedures will be eligible for this study. A total of 100 patients will be studied (control + treatment groups). All blocks will be placed in the sitting position utilizing a midline approach at L3-4 with a 25# needle. The control group will receive 4 ml of 0.5% bupivacaine plus 0.2 ml normal saline. The treatment group will receive 4 ml of 0.5% buivacaine plus 0.2 ml fentanyl. Quality of analgesia will be assessed using the following parameters: 1) level of pinprick at 10, 20, 30 and 60 minutes, 2) patient complains of pain on incision or tourniquet pain, 3) dosage of supplementary analgesics intraoperatively and in the recovery room. Occurrence of nausea, vomiting or pruritus will be recorded.

Progress: At the present time, too few patients have been entered on the study to predict any results or trends.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-25-90 Status: Completed  
 Title: Pressure Transducer Localization of Multi-Orificed CVP Catheters.

Start Date 6 Feb 90	Est Comp Date:
Principal Investigator Paul D. Mongan, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Richard C. Peterson, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 20	
Total Number of Subjects Enrolled to Date: 20	
Date of Periodic Review	Results

Objective(s): To develop a technique for accurate localization of the distal tip of a multi-orificed CVP catheter for the purpose of venous air embolism (VAE) aspiration.

Technical Approach: This study was conducted on 20 patients who were determined to need antecubital line placement for pressure monitoring or VAE prophylaxis. After placement of a 8.5 FR introducer sheath, a multi-orificed angiography catheter was positioned utilizing pressure waveform changes. The catheter will be advanced until a RV trace is obtained. The catheter was slowly withdrawn until the RV waveform is lost. At that point the catheter was withdrawn an addition 5 cm. and secured. A portable CXR was obtained and the position recorded in relation to the SVC-RA junction.

Progress: Results indicate that use of a RV waveform is a reliable method for locating a right atrial catheter to the high right atrium.

# Detail Summary Sheet

Date: 29 Nov 90	Proj No: C-26-90	Status: Ongoing
Title: The incidence of Spinal Headaches after Continuous Spinal Anesthesia: The Role of Bevel Orientation.		

Start Date 13 Feb 90	Est Comp Date:
Principal Investigator (vice Culling) Donald B. Tollackson, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): The purpose of this prospective study is to determine what role, if any, bevel orientation plays in the incidence of postdural puncture headache (PDPH) after continuous spinal anesthesia (CSA). In addition, we will attempt to correlate headache severity, and the type of treatment necessary with bevel orientation during dural puncture.

Technical Approach: Approximately 30 patients will be randomly divided into two groups differing only in bevel orientation (parallel to the dural fibers versus perpendicular) of the needle during dural puncture. CSA will be given in the usual manner as appropriate for the surgical procedure. Patients will be followed for 96 hours postoperatively and the incidence of PDPH determined for each group. Specific treatment necessary for any PDPH will be noted for both groups.

Progress: No progress has been made due to release of MAJ Culling from active duty. Enrollment of patients by the new principal investigator will begin in the near future.

# Detail Summary Sheet

Date: 27 Aug 90 Proj No: C-27-90 Status: Completed  
 Title: The Use of Tessalon Pearles for Rapid Topical Anesthesia of the Oropharynx.

Start Date 13 Feb 90	Est Comp Date:
Principal Investigator Paul D. Mongan, MD, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Robert D. Culling, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 40	
Total Number of Subjects Enrolled to Date: 40	
Date of Periodic Review	Results

Objective(s): a) To assess the adequacy of topical anesthesia of the oropharynx with Tessalon Pearles for the purpose of awake sedated intubations. b) To determine the time required to obtain adequate topical anesthesia with Tessalon Pearles. c) To compare a and b with similar data generated on a cohort who will have oropharyngeal anesthesia with local anesthesia gargle and superior laryngeal nerve blocks.

Technical Approach: 40 ASA I and II patients scheduled for general anesthesia were studied. All patients were nasotracheally intubated after naso- and oropharyngeal anesthesia was performed. Patients were randomized into 2 groups. Both groups had nasal and tracheal anesthesia in the same manner. Group I was given 2 Tessalon Pearles to crush in their mouth and then swallow. Group II had superior laryngeal nerve blocks with 4cc of 1% lidocaine and 5 cc of 2% viscous lidocaine for oropharyngeal anesthesia. Nerve blocks and topicalization were performed and timed by the principal investigator. Nasotracheal intubation was performed by a staff anesthesiologist blinded to method of oropharyngeal anesthesia. The intubator graded intubation conditions. Patients were interviewed postoperatively for comfort during the procedure and questioned for sore throat and other complaints.

Progress: Tessalon Pearles were equivalent to superior laryngeal nerve blocks as an adjunct to preparation of the airway for awake intubation. Tessalon Pearles resulted in less time to obtain oropharyngeal anesthesia ( $P < .005$ ) than superior laryngeal nerve blocks.

Conclusion: Tessalon Pearles are a viable adjunct for oro-pharyngeal anesthesia for awake sedated intubation.

# Detail Summary Sheet

Date: 28 Sep 90 Proj No: C-30-90 Status: Ongoing  
 Title: Low Frequency Positive Pressure Ventilation (LFPPV) and Extra-corporeal CO2 Removal (eccor) in Severe Acute Respiratory Failure.

Start Date 13 Feb 90	Est Comp Date:
Principal Investigator Robert J. Johnson, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Cardiothoracic Surgery	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To assess the efficacy of LFPPV with ECCOR in adult patients with severe acute respiratory failure that have not responded to conventional ventilatory therapy, and whose mortality is judged to be greater the 90% with continued conventional therapy. These patients are currently being treated at Brooke Army Medical Center (BAMC) with continued conventional ventilatory support and have an expected mortality of greater than 90%.

Technical Approach: After anticoagulation, veno-veno extracorporeal bypass through a membrane oxygenator will be instituted at 20-30% of the cardiac output, and the conventional ventilator will be weaned to 5 breaths per minute, with continuous oxygen delivered via a catheter placed in the patient's endotracheal tube. As oxygenation improves the FIO<sub>2</sub>, the ventilator will be decreased to 0.5, followed by that of the membrane lungs. The patient then will be weaned from ECCOR. When the patient is able to support ventilation with a continuous positive airway pressure of 10-15 cmH<sub>2</sub>O at FIO<sub>2</sub> of 0.4, or on low frequency intermittent mandatory ventilation for at least six hours, without gas exchange in the membrane, the support system will be disconnected.

Progress: No progress has been made due to lack of funding to obtain the nursing support required.

# Detail Summary Sheet

Date: 29 Oct 90	Proj No: C-32-90	Status: Ongoing
Title: Intravenous Injection of Prostaglandin E1 for Erectile Impotency		

Start Date 13 Feb 90	Est Comp Date:
Principal Investigator Ramon L. Caballero, CPT	Facility Brooke Army Medical Center
Dept/Svc Urology Service	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the benefit of intracavernous penile injection of prostaglandin E1 in patients with erectile impotency.

Technical Approach: Patients will complete a questionnaire, undergo a full genital exam and battery of blood tests at the beginning of the study. Part 1 of the study will involve in office, physician supervised injections into the penile bodies at weekly intervals until an adequate dose is reached not exceeding a maximum predetermined dose. Part 2 will involve home self-injections in patients who are successful in phase 1.

Progress: Shortly after approval of this protocol, the principal investigator began his rotation at Wilford Hall USAF Medical Center. Patient enrollment will begin upon return to BAMC.

# Detail Summary Sheet

Date: 14 Aug 90 Proj No: C-38-90 Status: Ongoing  
 Title: The Effect of Rapid Sequence Induction of Anesthesia on Intraocular Pressure.

Start Date 12 Mar 90	Est Comp Date:
Principal Investigator Thaddeus J. Krolicki, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department Surgery/Ophthalmology	Associate Investigators: Stephen Gates, CPT, MC Calvin E. Mein, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 7	
Total Number of Subjects Enrolled to Date: 7	
Date of Periodic Review	Results

Objective(s): This study is designed to help resolve current conflicts between the ophthalmologic and anesthesia literature regarding optimal anesthetic techniques for the induction of general anesthesia in non-fasting patients with perforating ocular trauma. We propose to study the effect on IOP of a widely accepted rapid sequence induction regimen consisting of succinylcholine, lidocaine, fentanyl, curare, and sodium thiopental.

Technical Approach: We propose to study the combined effect of succinylcholine, curare, lidocaine, fentanyl, and sodium thiopental on IOP in a group of 30 normal patients undergoing general anesthesia. We will compare each subject's preoperative IOP, obtained using a hand-held Perkins tonometer, with their IOPs measured during the first 5 minutes of induction.

Progress: Preliminary results indicate rapid sequence induction increases intraocular pressure 6-8 mm Hg with maximum at 2 minutes post-induction.

Initial results, presented at the 1990 Alamo City Ophthalmology Clinical Conference, were awarded first place for excellence of presentation.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-42-90 Status: Ongoing  
 Title: Does DDAVP Alter Post-Cardiopulmonary Blood Loss in High Risk Patients?

Start Date 27 Mar 90	Est Comp Date:
Principal Investigator Paul D. Mongan, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Michael Hosking, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 23	
Total Number of Subjects Enrolled to Date: 23	
Date of Periodic Review	Results

Objective(s): 1) To evaluate the effect of DDAVP infusion on TEG parameters of platelet function when they are significantly (>25%) reduced from pre-CPB values. 2) To evaluate the effect of DDAVP infusion on post-CPB bleeding in patients with abnormal post-CPB TEG. 3) To evaluate the hemodynamic effect of DDAVP infusion on post-CPB patients. 4) To compare objectives 1-3 with a control infusion of physiologic saline in a prospective randomized and blinded manner.

Technical Approach: Prior to cardiopulmonary bypass procedure, blood will be obtained for routine clotting tests by thromboelastogram (TEG). During the surgical procedure, repeat TEG will be performed. If TEG reveals a decrease in platelets, DDAVP mixed with saline or saline alone will be given.

Progress: No reportable data are available at this time.



# Detail Summary Sheet

Date: 14 Sep 90      Proj No: C-44-90      Status: Ongoing  
 Title: A Controlled, Covariate Analysis of Radical Prostatectomy versus  
 Radiation Therapy for Adenocarcinoma of the Prostate.

Start Date 27 Mar 90	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ	Facility Brooke Army Medical Center
Dept/Svc Urology Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the relative merit of radical prostatectomy versus radiation therapy for organ-confined carcinoma of the prostate.

Technical Approach: Records of patients treated for carcinoma of the prostate prior to 1 January 1983 will be reviewed. Using a matching technique, patients undergoing radiation therapy will be matched with patients who have undergone radical prostatectomy. This study is designed as a multifactorial analysis of the relative merits of these two techniques using multiple endpoints and covariate analysis.

Progress: Data collection from BAMC completed. Data have been submitted from FAMC and MAMCY and the data from WRAMC are currently completed and are being mailed. At the present, data are being entered into a computer spread sheet and data analysis is pending.

# Detail Summary Sheet

Date: 14 Sep 90      Proj No: C-56-90      Status: Ongoing  
 Title: Dysesthetic Pain: A Blinded and Controlled Study of Treatment with Capsaicin 0.075%.

Start Date 24 Apr 90	Est Comp Date:
Principal Investigator Emil J. Menk, MD, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Anesthesia and Operative Service	Associate Investigators: Stuart Sinoff, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): This study is designed to evaluate the efficacy of topical capsaicin cream 0.075% vs placebo in the treatment of dysesthetic pain syndromes.

Technical Approach: Patients meeting the inclusion criteria will apply Capsaicin cream, 0.075%, to the affected area four times daily for six weeks. Follow-up evaluations will be done at 2, 4 and 6 weeks.

Progress: .075% Capsaicin which requires an IND has not yet been received by the company. MAJ Sinoff, who is not at Walter Reed, will contact the company concerning the multi-institutional study.

# Detail Summary Sheet

Date: 14 Sep 90 Proj No: C-57-90 Status: Ongoing  
 Title: Ace/Olerud Posterior Segmental Fixation Spine System.

Start Date 1 May 90	Est Comp Date:
Principal Investigator Jeffrey D. Coe, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Surgery/Orthopaedic Surgery Svc	Associate Investigators: Robert Harris, CPT, MC
Key Words: Spinal fracture Pedicle screws Internal fixation Spinal fixation	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review	Results

Objective(s): To evaluate the safety and effectiveness of the Posterior Segment Fixator (PSF) in the management of unstable fracture segments of the thoracolumbar and lumbar vertebra (T10 to L5) when compared to other similar systems as reported in the literature.

Technical Approach: This is a multi-center study. The system will be used for patients diagnosed with fractures of the vertebrae at the T10 to L5 levels. Patients will be followed for a period of 24 months after device insertion. At one year the device will be removed in those cases where fusion has not occurred.

Progress: All three patients have stable fixation without evidence of deformity progression. Complications include two deep wound infections successfully treated with a single I&D and closure over suction drainage tubes. One patient with a mixed conus/cauda lesion had slight progression of nerve deficit. The patient had 90% cauda compromise reduced to 60% with posterior spinal fusion, then 0-10% with anterior decompression with shunt fusion.

# Detail Summary Sheet

Date: 30 Oct 90 Proj No: C-61-90 Status: Ongoing  
 Title: Swimming and Myringotomy Tubes

Start Date 12 May 90	Est Comp Date:
Principal Investigator Jeffrey M. Braaten, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators: Kweon Stambaugh, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 63	
Total Number of Subjects Enrolled to Date: 83	
Date of Periodic Review	Results

Objective(s): To determine the incidence of ear infection while swimming with middle ear ventilation tubes.

Technical Approach: All patients undergoing myringotomy and insertion of ventilation tubes that are intact and patent during the swimming season, June - September, will be included in the study. Swimmers and non-swimmers will be randomized by a table of random numbers. A variety of ventilation tubes will be placed based on the surgeons personal preference. Patients will be seen routinely two weeks postoperatively and then every three months thereafter until the tubes are extruded. Patients will be given a claender and questionnaire. The days swimming, the number of ear infecitons, and their relationship to an upper respiratory infection will be recorded.

Progress: Patient data sheets are being returned to ENT by the patients. Preliminary/verbal reports show no increased incidence of otitis media with swimming.

# Detail Summary Shee

Date: 2 Oct 90 Proj No: C-66-90 Status: Ongoing  
 Title: Does Nitroglycerin Infusion Decrease the Incidence of Pre-Cardiopulmonary Bypass Myocardial Ischemia?

Start Date 15 May 90	Est Comp Date:
Principal Investigator Paul D. Mongan, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Michael Hosking, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review	Results

Objective(s): 1) To determine the incidence of pre-CPB myocardial ischemia as diagnosed by transesophageal electrocardiogram (TEE). 2) To evaluate if prophylactic IV nitroglycerin infusion at a rate of 1 mcg/kg/min provides effective prophylaxis for pre-CPB myocardial ischemia which is unrelated to indices of oxygen demand. 3) To compare IV NTG with a control infusion of physiologic saline. 4) To evaluate if changes in hemodynamic variables (HR +/-10%, BP +/-20%) affects the incidence of pre-CPB ischemia. 5) To evaluate if pre-CPB ischemia is an independent predictor of postoperative cardiac morbidity.

Technical Approach: This is a prospective blinded study which will be conducted on 120 patients randomized into two groups. Group I will receive an infusion of physiologic saline and group II will receive an infusion of IV NTG at a rate of 1 mc/kg/min. This population size provides for a power of .8 and  $p < .05$  if pre-CPB myocardial ischemia is reduced by 20%.

Progress: Because of delay in delivery of second TEE machine, coordination with cardiology has been difficult for sharing their equipment.

# Detail Summary Sheet

Date: 14 Aug 90 Proj No: C-67-90 Status: Ongoing  
 Title: Pressure Monitoring in Casts Following Acute Fractures

Start Date 15 May 90	Est Comp Date:
Principal Investigator James P. Stannard, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Allan L. Bucknell, COL, MC Robert M. Harris, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 9	
Total Number of Subjects Enrolled to Date: 9	
Date of Periodic Review n/a	Results

Objective(s): To evaluate the clinical usefulness of pressure sensing devices incorporated into casts following acute fractures.

Technical Approach: The Cast Alert pressure sensing device will be applied randomly to 24 out of 48 consecutive patients with forearm fractures considered severe enough to warrant admission to the hospital for elevation and neurovascular checks. Two pressure sensors will be applied dorsally (one proximal and one distal to the fracture) and one will be applied volarly. While the patients are hospitalized, they will have neurovascular checks every 2 hours. Following each evaluation, the numerical pressure will be recorded from the Cast Alert device.

Progress: Nine patients have met the inclusion criteria and entered into the study. Early results indicate a good correlation between cast alert pressure readings and compartment pressures. Enough patients have not been entered to make any conclusions regarding clinical usefulness. There have been no adverse reactions as a result of the Cast Alert device or the study.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-68-90 Status: Ongoing  
 Title: Automated Perimetry in the Evaluation of Patients with Dermatochalasis

Start Date 1 Jun 90	Est Comp Date:
Principal Investigator Henry D. Hacker, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators: Donald A. Holsten, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 23	
Total Number of Subjects Enrolled to Date: 23	
Date of Periodic Review	Results

Objective(s): To investigate the application of automated perimetry in the evaluation of patients of patients for upper lid blepharoplasty:

a. As an aid to the assessment of visual field loss in patients with dermatochalasis;

b. Documentation for medicolegal and insurance purposes.

Technical Approach: Thirty patients will undergo a complete oculoplastic evaluation prior to and at 4 to 6 weeks after operation. Measurements obtained during each exam will include: vertical tissue height, margin reflex distance, lid crease height, levator function, and amount of lagophthalmos (if any). Visual fields on the Allergan-Humphrey Model 630 and 35 mm slides of the eyes will be obtained during each examination.

Progress: We are continuing to accumulate visual field data and lid measurements. Automated perimetry appears to effectively document visual field increase in about 70% of patients.

# Detail Summary Sheet

Date: 14 Sep 90	Proj No: C-75-90	Status: Ongoing
Title: Analysis of Footgear and Landing Positions in Parachute Landings		

Start Date 19 Jun 90	Est Comp Date:
Principal Investigator CPT James P. Stannard	Facility Brooke Army Medical Center
Dept/Svc Department Surgery/Orthopaedics	Associate Investigators: Allan L. Bucknell, COL, MC Robert M. Harris, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review	Results

Objective(s): To evaluate the effect on energy absorbed by a paratrooper during Parachute Landing Falls (PLF's) with varying footgear. Energy absorption will be evaluated using Fuji Prescale Pressure Detecting Film in footgear. The second objective of the study is to evaluate differences in energy absorbed using different landing positions.

Technical Approach: The initial portion of the study will involve jumps from a 75 inch high platform with one of the following six types of footgear: 1) Jump boots, 2) Jungle boogs, 3) Jump boots with Sorbathane insoles, 4) Jungle boots with Sorbathane insoles, 5) Nike Air Max Cross Trainer shoes, and 6) Asics GT Xpress Gel padded shoes. All jumps will be performed by the principal investigator, an experience Army paratrooper. Ten jumps will be performed with each type of footgear. All landings during this phase of the study will be front left. The pressure sensitive film will be evaluated with a densitometer to determine the energy transmitted to the soldier during the PLF.

Progress: Five jumps have been performed and data collected. The data have been analyzed using a densitometer and demonstrated statistically significant improved energy absorption with the Nike and Asics shoes compared to jump boots. Trends of improved energy absorption with Sorbathane were also identified. We plan to analyze the remainder of the data using a direct computer/camera hook-up which is presently being installed.



# Detail Summary Sheet

Date: 18 Sep 90 Proj No: C-76-90 Status: Ongoing  
 Title: Analysis of Mesenteric Venous Blood for Malignant Cells in the Presence of Tumor Manipulation in Colon Cancer

Start Date 19 Jun 90	Est Comp Date:
Principal Investigator CPT Frank R. Robertson	Facility Brooke Army Medical Center
Dept/Svc Department Surgery/General Surgery	Associate Investigators: Janice Grassell
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 7	
Total Number of Subjects Enrolled to Date: 7	
Date of Periodic Review	Results

Objective(s): To determine if intraoperative tumor manipulation results in shedding of malignant cells into the mesenteric venous blood in patients with adenocarcinoma of the colon.

Technical Approach: In the operating room, the proximal and distal portion of the segment of colon to be removed will be divided. The mesentery will be taken down with the exception of the primary feeding artery and draining vein. The vein will then be divided and a sample of blood obtained. The tumor will be compressed gently in a controlled, reproducible manner and a second sample of blood will be obtained. This blood will be analyzed for the presence or absence of tumor cells. Conventional staining techniques and flow cytometry using a cancer specific monoclonal antibody will be used.

Progress: This protocol has been progressing without incident. Participation of qualifying patients has been 100%. There have been no complications.

Most of the seven patients enrolled so far have advanced cancer. In this subset of patients, the data obtained appears to indicate that adenocarcinoma cells are shed into the mesenteric circulation with tumor manipulation. Statistically significant results await further study.

# Detail Summary Sheet

Date: 2 Oct 90                      Proj No: C-89-90                      Status: Ongoing  
 Title: Attitudes and Practice Concerning Screening for Prostate Cancer Among  
 Urologists in the United States

Start Date 2 Aug 90	Est Comp Date:
Principal Investigator	Facility
Ian M. Thompson, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Surgery/Urology	Eric S. Zeidman, MAJ, MC
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the current practice in the United States of urologists regarding screening for prostate cancer and to determine if this practice is similarly being used by the physicians themselves.

Technical Approach: With the advent of transrectal ultrasonography of the prostate and prostate specific antigen, many members of the urology community are currently practicing screening with one or both of these modalities in addition to digital rectal examination. A questionnaire will be mailed to urologists requesting information regarding screening tests they are employing for the detection of prostate cancer.

Progress: The questionnaires have been mailed.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-91-90 Status: Ongoing  
 Title: The Incidence of Prostatism in Older Males Presenting for Herniorrhaphy

Start Date 30 Aug 90	Est Comp Date:
Principal Investigator Kevin C. Shandera, CP, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To determine the incidence of prostatism in males 40 years of age and older who present for herniorrhaphy.

Technical Approach: One hundred consecutive men scheduled for herniorrhaphy will undergo urodynamics evaluation in an attempt to detect asymptomatic or minimally symptomatic physiologically-significant bladder outlet obstruction secondary to prostatic hyperplasia. Should such obstruction be encountered, Urology consultation would be requested before herniorrhaphy is undertaken.

Progress: This is a new study. No reportable data are available.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-94-90 Status: Ongoing  
 Title: Protein Turnover, Pulmonary Amino Acid Flux, and Nitrogen Balance in Critically Ill Surgical Patients

Start Date 31 Aug 90	Est Comp Date:
Principal Investigator David W. Mozingo, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/SICU	Associate Investigators: William K. Becker, LTC, MC James M. Lamiell, LTC, MC R. Bernard Rochon, MAJ, MC Glen E. Gueller, SFC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To measure protein turnover, amino acid flux, and nitrogen balance across the lungs in critically ill surgical patients.

Technical Approach: To measure how the lung can change amino acids, glycine will be infused. Before, during, and after the infusion blood will be drawn. Samples of urine will be obtained for analysis.

Progress: This is a new study.

# Detail Summary Sheet

Date: 2 Oct 90      Proj No: C-96-90      Status: Ongoing  
 Title: Effect of Nutritional Support on Immune Function in Critically Ill  
 Patients - a Component Study

Start Date 31 Aug 90	Est Comp Date:
Principal Investigator	Facility
David W. Mozingo, CPT, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Surgery/SICU	William K. Becker, LTC, MC
Key Words:	James M. Lamiell, LTC, MC
	R. Bernard Rochon, MAJ, MC
	Glen E. Gueller, SFC
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To compare the efficacy of various nutritional components specifically designed to promote immune function in patients.

Technical Approach: This is a randomized, prospective, double-blind trial of enteral nutritional products containing components thought to promote immune function in surgical patients requiring enteral nutrition support. Patients will be randomized to receive one of two solutions as their enteral support. Patients will receive either IMPACT or a control solution (isocaloric/Isonitrogenous).

Progress: This is a new study. No reportable data are available.

# Detail Summary Sheet

Date: 24 Oct 90 Proj No: C-97-90 Status: Ongoing  
 Title: A 16-Week Double Blind Placebo-Controlled Dose-Response Study Using Doxazosin Tablets for the Treatment of Benign Prostatic Hyperplasia in Patients with Mild to Moderate Essential Hypertension

Start Date 7 Sep 90	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Eric S. Zeidman, MAJ, MC Joseph P. Johns, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine the safety and efficacy of doxazosin tablets in the treatment of patients with benign prostatic hyperplasia and mild to moderate essential hypertension.

2) To determine if there are any changes in symptomatology and urodynamic variables related to dose and duration of therapy.

Technical Approach: The study is designed as a double-blind, placebo-controlled, parallel-trial with five treatment groups: placebo and four different doses of doxazosin (2, 4, 8 and 12 mg). This study will be divided into four phases lasting a total of 16 weeks: Phase I (Screening), minimum of one week; Phase II (placebo), two weeks; Phase III (titration), five weeks and Phase IV (efficacy), nine weeks. All medications are to be taken in the morning. After all evaluations for a given visit have been completed, the patient will be dosed from the next week's medication card.

Progress: This is a new study.

# Detail Summary Sheet

Date: 24 Oct 90 Proj No: C-98-90 Status: Ongoing  
 Title: An Open-Label Extension Study Using Doxazosin Tablets for the Treatment of Benign Prostatic Hyperplasia in Patients with Mild to Moderate Essential Hypertension

Start Date 7 Sep 90	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Eric S. Zeidman, MAJ, MC Paul Desmond, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine the long-term safety and efficacy of doxazosin tablets in hypertensive patients with benign prostatic hyperplasia (BPH).

2) To obtain information regarding the optimal dose of doxazosin tablets required on a long-term basis for patients with BPH.

Technical Approach: Patients who successfully complete the 16 week double blind study may enter the open label extension study. They must do so within one week. Patients who withdrew from the 16 week study, after randomization, due to adverse experiences or lack of efficacy may also enter. The study is designed as an open-label, long-term, follow-up trial to the initial 16 week study. All patients in the open label trial will initially receive 1 mg of doxazosin daily and will be titrated upward at two week intervals, one dose level at a time, to a daily dose of 2, 4, 8, or 12 mg. A patient's upward titration will be dependent upon their adverse experiences, blood pressure response and BPH symptomatology. Once an optimal dose is achieved, it will be maintained unless the investigator determines that an adjustment in dose (lower or higher) is medically indicated.

Progress: This is a new study.

# Detail Summary Sheet

Date: 24 Oct 90 Proj No: C-101-90 Status: Ongoing  
 Title: Clinical Study of the Surgitek Prostate Balloon Dilatation Catheter for Use in Males with Benign Prostatic Hyperplasia.

Start Date 13 Sep 90	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Eric S. Zeidman, MAJ, MC Paul Desmond, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To evaluate the safety and effectiveness of the SURGITEK® Prostate Balloon Dilatation Catheter in treating men with benign prostatic hyperplasia.

Technical Approach: Adult males age 18 years and over will comprise the study group. Up to 81 subjects with symptomatic benign prostatic hyperplasia will be included in the study. Following local anesthesia, the appropriate size balloon catheter will be positioned and the balloon inflated with sterile water and maintained at a recommended pressure for approximately 10-15 minutes. When the amount of dilatation desired is completed, the dilatation catheter will be deflated and removed.

Progress: This is a new study.



# Detail Summary Sheet

Date: 24 Oct 90 Proj No: C-102-90 Status: Ongoing  
 Title: Treatment of Bladder Carcinoma (T<sub>a</sub>-T<sub>3a</sub> and CIS) with Intravesical Interleukin-2 (Cetus): Phase II.

Start Date 13 Sep 90	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Eric S. Zeidman, MAJ, MC Paul Desmond, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To determine the effectiveness (response rate) of intravesicular IL-2 in the treatment of bladder carcinoma stages T<sub>a</sub>-T<sub>3a</sub> and carcinoma in situ (CIS).

2) To determine the toxicity of intravesicular IL-2 in such patients.

Technical Approach: Patients must have histologically proven primary bladder carcinoma (any grade). Patients are eligible if they have any of the following stages: (a) recurrent stage T<sub>a</sub> or T<sub>1</sub>; (b) multiple tumors (> 3) at presentation; (c) a primary tumor > 3 cm. regardless of depth of invasion; (d) T<sub>2</sub>; (e) T<sub>3a</sub>; (f) carcinoma in situ. Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

# Detail Summary Sheet

Date: 16 Oct 90 Proj No: C-48-90 Status: Ongoing  
 Title: Evaluation of a Novel Aminoglycoside Dosing Nomogram

Start Date 27 Mar 90	Est Comp Date:
Principal Investigator Thomas C. Shank, CPT, MS	Facility Brooke Army Medical Center
Dept/Svc Pharmacy Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To evaluate the predictive accuracy of a novel aminoglycoside dosing nomogram.

Technical Approach: Adult male and female patients who have an infection requiring gentamicin will be admitted to the study. When the patients' serum gentamicin level has reached steady state, one of the study participants will administer one dose of gentamicin via a syringe pump and draw both nadir (trough) and peak serum gentamicin samples. Each sample will be divided into two parts, one will be sent to the DPALS laboratory for routine analysis and the other will be analyzed in DCI by one of the study participants.

Progress: No progress has been made due to nonavailability of the a syringe pump which is on order.

# Detail Summary Sheet

Date: 15 May 90 Proj No: C-58-88 Status: Terminated  
 Title: Joint Mobilization Plus Active Range of Motion Exercises versus Home  
 Active Range of Motion Exercises in the Treatment of Adhesive Capsulitis

Start Date 3 Jun 88	Est Comp Date:
Principal Investigator Carol J. Johnson, 1LT, SP	Facility Brooke Army Medical Center
Dept/Svc Physical Medicine & Rehabilitation Svc	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 5	
Total Number of Subjects Enrolled to Date: 12	
Date of Periodic Review 14 May 90	Results Terminated

Objective(s): To compare the effectiveness of joint mobilization plus active range of motion (AROM) exercises versus a home AROM exercise program.

Technical Approach: Male and female patients, 40-70 years of age, with a diagnosis of frozen shoulder are randomly assigned to one of two treatment groups. Group A receives joint mobilization three times a week as well as a daily home exercise program. Group B is on a home exercise program only (wand, pendulum, towel stretch, wall climbing, etc.). Subjects will discontinue joint mobilization when functional AROM is restored (150° flexion, 130° abduction, 60° internal and external rotation). Shoulder AROM measurements are being taken initially, at 2 weeks, 1 month, 2 months and 3 months.

Progress: This study was terminated due to inability to involve adequate number of patients.

# Detail Summary Sheet

Date: 28 Nov 90 Proj No: C-51-90 Status: Terminated  
 Title: A Comparison of Static Grip Strength Measurements on Two Evaluation Devices.

Start Date 27 Mar 90	Est Comp Date:
Principal Investigator Pat Harvey, CPT	Facility Brooke Army Medical Center
Dept/Svc Occupational Therapy Service	Associate Investigators: Richard Jansen, MAJ, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To compare the Jamar dynamometer and the BTE-WS as instruments used for evaluating static grip strength and to establish norms for use of the BTE-WS as an evaluation tool for the measurement of static grip strength among young adults.

Technical Approach: A sample of 100 female and male subjects, between 18 and 30 years of age, will be selected from a population of military occupational and physical therapy students assigned to the Academy of Health Sciences. Screening criteria for each individual will include an assessment of previous upper extremity musculoskeletal or neuromuscular pathology via a verbal interview and examination if needed. Hand dominance for each will be determined. The Jamar dynamometer and BTE-WS will be employed to assess static grip strength throughout the study.

Progress: This study was terminated due to failure of the principal investigator to submit an annual report.

# Detail Summary Sheet

Date: 24 Oct 90 Proj No: C-100-90 Status: Ongoing  
 Title: An Epidemiologic Study of Training Injuries in an Officer Basic Training Course for Medical Professionals.

Start Date 10 Sep 90	Est Comp Date:
Principal Investigator Hope S. Hacker, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Physical Medicine & Rehab. Service	Associate Investigators: David P. Brown, CPT, MC James D. Wells, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

- Objective(s): 1) To document the incidence and categories of related injuries among male and female trainees and time lost from training secondary to injuries.
- 2) To determine the impact of entry level physical fitness and related factors on the risks of injury in males and females.
- 3) To establish relative risks of injury for males and females.
- 4) To document the illness among trainees and to contrast the incidence of illness and associated disability with that of injury.

Technical Approach: Subjects will be one class of Academy of Health Sciences Officer Basic Training Course which is comprised of approximately 300 males and females between the ages of 20 and 52. All consenting individuals will fill out a physical activity and injury entry questionnaire. A subsequent injury questionnaire will be filled out just prior to completion of the training course.

Progress: This is a new study.

# Detail Summary Sheet

Date: 29 Nov 90 Proj No: C-42-88 Status: Ongoing  
 Title: Evaluation of Routine Human Immunodeficiency Virus (HIV) Screening Program in Hospitalized Patients.

Start Date 29 Mar 88	Est Comp Date:
Principal Investigator Jenice N. Longfield, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Preventive Medicine Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1205	
Total Number of Subjects Enrolled to Date: 1205	
Date of Periodic Review 23 Mar 90	Results Continue

Objective(s): To assess the impact of implementing a routine HIV screening program in hospital admissions in a tertiary care hospital in an area of low prevalence for the HIV infection.

Technical Approach: Evaluate implementation of routine screening of hospital admission on selected medicine and surgery wards via a questionnaire requiring data from chart review. Subsequent correlation with laboratory test results and laboratory statistics. Outcome variables include acceptance rate for screening by nonactive duty patients, rate of positive test results, hospital day when results become available, etc. Outcome variables will be categorized by ward, service, and demographic characteristics.

Progress: There have been 1144 study subjects enrolled for analysis after deletion for duplicate hospitalizations. Preliminary data analysis indicates: eliminated duplicate admissions, analyzed for demographic characteristics, active duty status, status of consent for HIV testing and results of serological analysis on those civilians consenting has been completed. Data are being analyzed.

# Detail Summary Sheet

Date: 15 May 90      Proj No: C-83-89      Status: Terminated  
 Title: Measles Contacts: Immune Response to Post Exposure Immunization

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Jenice Longfield, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Preventive Medicine Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review 14 May 90	Results Terminate

Objective(s): To evaluate measles antibody immune status of contacts pre- and post- vaccination relative to subsequent disease attack rates.

Technical Approach: Multiple outbreaks of measles in the United States in 1989 have demonstrated the failure to eradicate this disease using current immunized guidelines. This prospective followup of exposed contacts with antibody evaluation pre- and post- measles (re-) immunization will provide scientific data useful for future outbreak control and immunization guidance for both civilian and military personnel.

Progress: No new patients enrolled since previous 6. No measles outbreak in San Antonio in the past yuear. However, epidemic continues in other parts of texas, and a recurrent epidemic could occur in the future. If a significant measles outbreast does occur, the study will e resubmitted.

### Detail Summary Sheet

Date: 16 Oct 90	Proj No: C-109-89	Status: Completed
Title: Cold Conduction Through Various Casting Media		

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator 2LT Bryan L. Boyea	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: 2LT Colleen E. Beven CPT William C. Byers 2LT Brent S. Ferguson
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

**Objective(s):** To quantify the conduction of cold through moist plaster casting, fiberglass casting, and Gel-O-Casts by determining the absolute temperature change beneath each media.

**Technical Approach:** Thirty-three active duty Army male volunteers, 18-31, were studied. The three casting media were formed into 10x10 cm square inserts. The plaster strips were dipped into warm water (45° C), excess water was removed, and they were laminated to a thickness of ten layers over two uniform layers of standard 100% cotton cast padding. The fiberglass was dipped into 38° C water and laminated in six layers. Two uniform layers of standard 100% synthetic cast padding were inserted beneath the fiberglass media and patient just prior to study. The plaster casting was cured for approximately four hours. The Gelocast was laminated to form eight layers, did not require padding, and was formed into squares just prior to use.

The inserts were placed in an insulative foam framework which was composed of 1.0 cm thick poly foam. This framework had four 10 x 10 cm cutouts to allow random placement of the three casting media with an open area for control. A Two ply plastic bag was placed over the control cutout to prevent condensation from reaching the subjects' skin. This arrangement allowed simultaneous application of ice to the control cutout and each media. The ice slush was applied for 45 minutes. Temperature readings at the media to skin interfact were monitored and recorded at five minute intervals for a total of 65 minutes.

**Progress:** Statistical analyses revealed that moist plaster cast and fiberglass cast significantly limited cooling compared to direct ice contact. Moist plaster casting material allowed significantly greater cooling than fiberglass



C-109-89 (continued)

casting material. Gelocast bandage allowed greater cooling than direct ice application, but this difference was not statistically significant. Results support the use of ice over moist plaster and Gelocast both post-injury and postoperatively. However, the use of ice over fiberglass is questioned.

### Detail Summary Sheet

Date: 16 Oct 90                      Proj No: C-110-89                      Status: Completed  
 Title: A Correlation Study Comparing Three Methods of Measuring Hamstring  
 Muscle Length as Compared to Sacral Angle Measurement

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator	Facility
2LT Anne D. Parson	Academy of Health Sciences
Dept/Svc	Associate Investigators:
Physical Therapy Section	2LT Donna M. Vargas
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine whether or not a correlation exists between straight leg raise measures of hamstring muscle length and sacral angle in the long sit position.

Technical Approach: Fifty caucasian active duty military soldiers ranging in age from 18-30 were asked to participate in the study. Hamstring length was measured in four positions: (1) SLR test with flat back; (2) SLR test with natural lumbar curve; (3) SLR test with opposite hip and knee flexed; and (4) Sacral angle measure with the long sit test. Testing was conducted over a period of no more than six weeks with 30 minutes allotted for testing each subject.

Progress: Statistical significance was determined using a Pearson's Product Moment with an a priori value of  $\alpha = 0.05$ . Only the straight leg raise test with opposite knee bent correlated at a statistically significant level ( $p = 0.01$ ). The results of this study suggest that the straight leg raise test with opposite knee bent should be adopted.

# Detail Summary Sheet

Date: 16 Oct 90      Proj No: C-111-89      Status: Completed  
 Title: Effects of Gender and Foot Dominance on Neural Conduction in Human Subjects

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator	Facility
Ens Gregory M. Stearne	Academy of Health Sciences
Dept/Svc	Associate Investigators:
Physical Therapy Section	2LT Patrick J. Duffy
Key Words:	2LT Cathy L. Frola
	2LT Steven P. Snider
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To investigate the effects of gender and foot dominance upon the dependent variable of neural conduction.

Technical Approach: Twenty male and twenty female subjects, 21 to 35 years of age, were studied. Neural conduction velocities, amplitudes of response, and distal motor latencies were determined for the tibial and peroneal nerves. Distal latencies and amplitudes of response were determined for the sural nerve. A series of t-tests comparing the differences in gender, dominance, and pairing between legs were used to analyze the data.

Progress: The findings indicated that neither gender nor foot dominance had a clinically significant effect on NC's in the tibial, peroneal, and sural nerves. These findings enable us to conclude that the charts of normal NC values used in electrodiagnostic labs need not take into account limb side, gender or foot dominance.

### Detail Summary Sheet

Date: 16 Oct 90      Proj No: C-112-89      Status: Completed  
 Title: The Effect of Portable Static Pelvic Traction on Lumbar Intervertebral Distraction with Subject in 90/90 Positioning

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator CPT Patricia I. Fitzgerald	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: CPT Sarah J. Pierre 2LT Rachel K. Evans MAJ Gary Dier CPT Ronald Shippee
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine whether the Granberg EZ Tract® portable traction unit is capable of producing the lumbar intervertebral distraction.

Technical Approach: Thirty six healthy active duty U.S. Army males were randomly assigned to either an experimental (TX) or control (NTX) group. TX subjects (n=19) received pelvic traction force of approximately 70% of their body weight in a posture of supine lumbar flexion; NTX subjects (n=17) were placed in a traction belt in the same posture without the application of a traction force. The pre-post treatment design utilized radiographic data obtained from the TX and NTX groups to quantify the effects of a TX force on distances between specified locations on individual vertebral bodies from L3 to S1. Distances between anterior (DA), middle (DM) and posterior (DP) locations on the vertebral bodies were measured from radiographs, using a photo-coordinate digitizer, at levels L3-4, L4-5, and L5-S1. The changes in distances between each pair of vertebral end plates at DA, DM and DP were calculated by subtraction.

Progress: A significant treatment main effect was found ( $p < 0.0001$ ) for TX and NTX. Difference scores across all locations were consistently greater in the NTX group. A significant interaction ( $p < 0.0405$ ) indicated that the magnitude of change between the vertebral bodies was not the same by level and location for each treatment group. These findings suggest that 10 minutes of SPITX, when applied to young healthy males, may decrease the distance between individual vertebral bodies from L3 to S1.

# Detail Summary Sheet

Date: 16 Oct 90 Proj No: C-113-89 Status: Completed  
 Title: The Use of Therapeutic Levels of Ultrasound Over Costochondral Articulations and Its Effect on the Electrical Activity of the Heart as Measured by Electrocardiograph

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator 2LT Clard D. Heath	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: 2LT Dona L. Muger 2LT Ellen P. O'Keefe 2LT D. Paulson MAJ David M. Slife
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): To determine if therapeutic levels of ultrasound applied to costochondral articulations will result in a change in the electrical activity of the heart as measured by surface scalar electrocardiogram.

Technical Approach: Thirty-nine healthy male active duty military personnel, ages 21-30, were asked to participate. Each subject acted as his own control. Potential subjects with a previous history of cardiac problems, an abnormal initial ECG reading, or who did not meet blood pressure or height and weight screening criteria were excluded from the study. Continuous ultrasound (US) at a frequency of 1.0 MHz and an intensity of 1.3 W/cm<sup>2</sup> was applied continuously over the second through fifth left costochondral articulations while ECG readings were taken at one minute intervals throughout the procedure. Means and standard deviations were calculated and compared to clinically normal values to determine treatment effects. The parameters observed were heart rate, P-R interval, QRS interval, Q-T interval, QTc interval, QRS axis and S-T segment. Comparisons were made between a sham US treatment and the actual US treatment for those parameters.

Progress: The P-R, QRS, Q-T and QTc intervals, and the QRS axis stayed within normal ranges during both treatments. In addition, no significant change was noted in the S-T segment or in the heart rate. These results indicate that a therapeutic level of US (1.0 MHz and 1.3 W/cm<sup>2</sup>) applied over the chest wall in healthy adult males does not cause a significant change in the electrical activity of the heart. This validates the clinical use of US, within these parameters, in the treatment of musculoskeletal chest wall abnormalities such as costochondritis.

### Detail Summary Sheet

Date: 16 Oct 90	Proj No: C-114-89	Status: Completed
Title: Analysis of Eight Crutch Measurement Techniques as Compared to Ideal Crutch Length		

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator 2LT Dawn M. Bauer	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: 2LT David C. Finch 2LT Karen P. McGough
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine which of eight crutch measurement techniques is most accurate to obtain ideal crutch length.

Technical Approach: The height of 107 active duty military personnel were measured for crutches using each of the following methods: 1) axillary fold to heel in supine, 2) olecranon to opposite third finger tip, 3) olecranon to opposite fifth finger tip, 4) 77% of height, 5) height minus 16 inches, 6) 77% of armspan, 7) armspan minus 16 inches, and 8) number of crutch holes showing. Both reported and actual heights were used. Mean square error indices (MSE) were computed as the average of the squared deviations of each subjects scores from his ideal crutch score as determined using established clinical parameters.

Progress: Of the methods studied, the two involving mathematical manipulation of reported height were the best predictors: 77% of height (MSE 1.90); height minus 16 inches (MSE 2.43). The poorest predictor was axilla to heel in supine (MSE 14.09). Two new formulae were derived using regression analysis. The formulae with the best fit were: actual height  $X .72 + 2$  inches (MSE 0.43); reported height  $X .68 + 4.8$  inches (MSE 0.51). Using these formulae, a quick reference table of crutch lengths by subject heights was presented.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-82-90 Status: Ongoing  
 Title: Interrater Reliability of Circumferential Body Fat Measurements.

Start Date 2 Aug 90	Est Comp Date:
Principal Investigator Edgar Torres, 2LT	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Robert E. Boyles, 2LT Shawn E. Humpries, ENS Danny J. McMillian, 2LT
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): To determine the interrater reliability of body fat measurements within a group that has watched vdeo tap #TVT 8-103 (training video) as compared to a group that has only read AR 600-9.

Technical Approach: Subjects will include 20 soldiers qualified to estimate body composition. Group A will viw the training video, while Group B begins the circumferential tape measure estimates. Measurements will be recorded from scales calibrated according ot manufacturer specifications.

Progress: This is a new study.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-83-90 Status: Ongoing  
 Title: Comparison of Intermachine Differences Among Kin-Com™, Bio-dex™, and Lido™ Isokinetic Devices Using Eccentric Peak Torque Values

Start Date 2 Aug 90	Est Comp Date:
Principal Investigator Kerrie Golden, 2LT, SP	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Sharon Morrisseau, 2LT, SP Janice Reese, 2LT, SP
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To determine the extent of intermachine differences among Kin-Com™, Bio-dex™, and Lido™ isokinetic dynamometers through the comparison of peak torque values testing eccentric quadriceps contraction in the seated position following the manufacturer's protocol.

Technical Approach: Thirty-six active duty army male and female subjects will be studied. Each subject will be positioned and stabilized to perform right knee extension according to the manufacturer's protocol for each machine except for Kin-COM for which the Cybex protocol will be used. Once the subject is positioned, procedural instructions will be read to the subject with no other verbal cues given. The subject will then perform a warm-up/practice trial of 5-10 sub-maximal repetitions and two maximal repetitions followed by a one minute rest period. Once the subject is sufficiently warmed up, he/she will perform five maximal test repetitions from which data will be collected.

Progress: No reportable data are available at this time.



# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-84-90 Status: Ongoing  
 Title: Correlation Study Comparing Two Methods of Measuring Hamstring Muscle Strength as Compared to Sacral Angle

Start Date 2 Aug 90	Est Comp Date:
Principal Investigator Sharon M. Yanicek, ENS, SP	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Rita Schubert, 2LT, SP Julie D. Seligson, 2LT, SP
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the relationship that exists between two methods of assessing hamstring muscle length, straight leg raise with contralateral hip and knee flexion (SLR-FX) and active knee extension (AKE) as compared to the sacral angle-long sit test (SA-LS).

Technical Approach: Both legs will be measured. One of the investigators will locate anatomical landmarks on the low back, hip, leg and ankle. Various points will be drawn on these landmarks with a skin marker. Three measurements of hamstring length will be taken. Two measurements will be taken while lying on the back. For the first measurement, the leg will be lifted with the knee straight until the hamstrings limit motion. For the second measurement the thigh will be lifted to 90 degrees allowing the knee to bend and then the knee will be extended until the hamstrings limit motion. A third measurement will be taken while sitting on a table with legs extended and attempting to touch the toes with the fingers.

Progress: This is a new study. No reportable data are available at this time.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-85-90 Status: Ongoing  
 Title: Normative Values for Flexion and Extension Motion of the Cervical, Thoracic and Lumbar Spine Using the Two-Inclinometer Method

Start Date 2 Aug 90	Est Comp Date:
Principal Investigator Linda R. Early, ENS, SP	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Judy M. Adams, CP, SP
Key Words:	David L. Bronner, 2LT, SP Catherine S. McDowall, 2LT, SP
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine normative values for cervical, thoracic, and lumbar sagittal motion in normal subjects.

Technical Approach: After completion of a questionnaire, the length of hamstring muscle will be screened. Appropriate landmarks at the occiput, T1 and T12 spinous process and the sacrum will be marked. In a standing position, spinal motion of each subject will be measured.

Progress: This is a new study.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: -90 Status: Ongoing  
 Title: The Effect of Therapeutic Application of Ice Over Costochondral  
 Articulations on the Electrocardiogram of the Normal Heart

Start Date 2 Aug 90	Est Comp Date:
Principal Investigator J. Parry Gerber, 2LT, SP	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Gary Gilbert, 2LT, SP Colleen Griffin, 2LT, SP Lonnie Hergott, 2LT, SP David M. Slife, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): To determine if the therapeutic application of topical ice applied to costochondral articulations will result in a change in the electrical activity of the heart as measured by surface scalar electrocardiogram.

Technical Approach: This study will examine 50 healthy male active duty military personnel. Each subject will act as his own control. After determining that the subject's electrocardiogram is normal, he will receive a topical ice massage over the left 2nd-5th costal cartilages for 8 minutes. An electrocardiogram will be recorded at two minute intervals throughout the ice massage, as well as immediately after the treatment. The electrocardiogram will be monitored for any possible changes throughout the course of the treatment.

Progress: This is a new study. No data are available.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-87-90 Status: Ongoing  
 Title: Comparison of the Cybex II™, Biodex Model B-2000™, and the Kincom™  
 Isokinetic Dynamometer Measurement of Concentric Isokinetic Strength at the Knee

Start Date 2 Aug 90	Est Comp Date:
Principal Investigator Patricia Beers, 2LT, SP	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Kathleen Galloway, 2LT, SP
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To compare intermachine measurement differences of peak torque values generated from tests of the knee on the Cybex II™, Biodex™, and Kincom™ isokinetic dynamometers in accordance with standard manufacturers protocols.

Technical Approach: Thirty subjects between the ages of 18 and 50 will be studied. Each will be tested on each dynamometer to attain their average peak torque in concentric knee extension and flexion. Data will be assessed using randomized blocks, repeated measures analysis of variance.

Progress: No reportable data are available.

# Detail Summary Sheet

Date: 2 Oct 90 Proj No: C-88-90 Status: Ongoing  
 Title: Normative Values for Ulnar Nerve Intersegmental Latencies Across the Elbow Utilizing an Equidistant Segmental Simulation Technique

Start Date 2 Aug 90	Est Comp Date:
Principal Investigator	Facility
Barry A. Jackson, 2LT, SP	Academy of Health Sciences
Dept/Svc	Associate Investigators:
Physical Therapy Section	Nikki L. Gifford, 2LT, SP
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To establish normative values for the segmental latencies of the ulnar nerve across the elbow using equidistant segmental stimulation technique.

Technical Approach: Forty subjects, ages 21 to 33, will be selected from the active duty population at Fort Sam Houston, TX. Segmental latencies, neural conduction velocities, and amplitudes will be measured for both ulnar nerves using a Cadwell 5200A electromyograph, stimulator, and surface electrodes. Data will be analyzed descriptively, including means, ranges and standard deviations using a 2-way ANOVA at .05 level of significance.

Progress: This is a new study. No reportable data are available.

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